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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS-4190-F]

RIN 0938-AT97

Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise regulations for the Medicare Advantage (MA or Part C) program, Medicare Prescription Drug Benefit (Part D) program, and Medicare Cost Plan program to implement certain sections of the Bipartisan Budget Act of 2018 and the 21st Century Cures Act. In addition, it will enhance the Part C and D programs, codify several existing CMS policies, and implement other technical changes.

DATES: Effective Date: These regulations are effective [Insert date 60 days after the date of publication in the **Federal Register**].

Applicability Dates: Except for §§ 422.166(a)(2)(i), 423.186(a)(2)(i), and 422.514(d)(1) and (2), the provisions in this rule are applicable beginning January 1, 2021. The changes to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) are applicable beginning January 1, 2022. The provisions of § 422.514(d)(1), are applicable beginning January 1, 2022. The provisions of §

422.514(d)(2) are applicable beginning January 1, 2023.

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SUPPLEMENTARY INFORMATION: CMS intends to address all of the remaining proposals from the February 2020 proposed rule in subsequent rulemaking. Therefore, CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022. Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that are already in effect, CMS reminds readers and plan sponsors that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act), CMS intends to implement these statutes consistent with their effective provisions.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs before the contract year 2021 MA plan bids (due by statute on the first Monday in June):

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018)
- The 21st Century Cures Act (hereinafter referred to as the Cures Act)

The rule also includes a number of changes to strengthen and improve the Part C and D programs, codifies in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other guidance documents, and implements other technical changes. We took a measured approach to review each provision proposed and focused finalizing in this first final rule those most helpful for bidding, those that address the Coronavirus Disease (COVID-19) pandemic and public health emergency, as well as those topics on which issuing a final rule now would advance the MA program.

While we intend to address the remaining proposals from the February 18, 2020, proposed rule (85 FR 9002) not included in this final rule in subsequent rulemaking, we are focusing in this final rule on more immediate regulatory actions. CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022. Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that are already

in effect,¹ CMS reminds readers and plan sponsors that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the SUPPORT Act, CMS intends to implement the statute consistent with its effective provisions.

2. Summary of the Major Provisions

a. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

The Cures Act (Pub. L. 114-255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with end stage renal disease (ESRD) and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021. We are codifying this change with revisions to §§ 422.50(a)(2), 422.52, and 422.110.

b. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

With this new enrollment option, the Cures Act also made several payment changes in the MA and original Medicare FFS programs. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will

¹ These include the following BBA of 2018 provisions: Improvements to Care Management Requirements for Special Needs Plans (SNPs); Coverage Gap Discount Program Updates; and Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts.

be covered under the original Medicare FFS program. Section 17006(c)(2) of the Cures Act also amended section 1851(i) of the Act, providing that CMS may pay an entity other than the MA organization that offers the plan in which the individual is enrolled for expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We are finalizing changes to our regulation at § 422.322 in accordance with these new statutory requirements.

c. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Consistent with how the original Medicare FFS program will cover costs of organ acquisitions for kidney transplants for individuals in an MA plan, section 17006(b) of the Cures Act also amended section 1853 of the Act to exclude these costs from the MA benchmarks used in determining payment to MA plans. Specifically, the Secretary, effective January 1, 2021, is required to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates. We are finalizing changes to our regulations at §§ 422.258(d) and 422.306 in accordance with these new statutory requirements.

d. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (CMS-4182-F) (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through

423.186. We have stated we will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time, we are finalizing the increased weight of patient experience/complaints and access measures from 2 to 4. We are also finalizing our proposal to directly remove outliers prior to calculating the cut points to further increase the predictability and stability of the Star Ratings system, but we are delaying the application of outlier deletion until the 2022 measurement year which coincides with the 2024 Star Ratings produced in October 2023. We are also finalizing removal of the Rheumatoid Arthritis Management measure. Finally, we are finalizing the update to the Part D Statin Use in Persons with Diabetes measure weighting category. Unless otherwise stated, data will be collected and performance measured using these rules and regulations for the 2021 measurement period and the 2023 Star Ratings. The remaining Star Ratings provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Those provisions include codifying additional existing rules for calculating MA Quality Bonus Payments ratings, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around consolidations when data are missing due to data integrity concerns, modifying the extreme and uncontrollable circumstance policy for multiple year-affected contracts and to clarify rules when data are missing due to data integrity concerns, and additional technical clarifications.

e. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We are finalizing our proposal to amend the MA medical loss ratio (MLR) regulation at § 422.2420 so that the incurred claims portion of the MLR numerator includes all amounts that an MA organization pays (including under capitation contracts) for covered services. Currently, incurred claims in the MLR numerator include direct claims paid to providers (including under

capitation contracts with physicians) for covered services furnished to all enrollees under an MA contract. This amendment will also include in the incurred claims portion of the MLR numerator amounts paid for covered services to individuals or entities that do not meet the definition of “provider” as defined at § 422.2.

We are finalizing our proposal to codify in our regulations at §§ 422.2440 and 423.2440 the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the May 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule). It is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we codify these definitions and factors in the applicable regulations.

Additionally, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA medical savings account (MSA) contracts that receive a credibility adjustment. The deductible factor serves as a multiplier on the applicable credibility adjustment. This additional adjustment for MA MSAs is appropriate because the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. This is the case because high-deductible health plan enrollees’ medical expenses must exceed a higher threshold before the plan begins to incur claims costs that can be included in the MLR numerator. The deductible factor reduces the risk that an MSA contract will fail to meet the MLR requirement as a result of random variations in claims experience. We are

finalizing our proposal to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158.

f. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

We are strengthening network adequacy rules for MA plans by codifying our existing network adequacy methodology and finalizing policies that address maximum time and distance standards in rural areas, telehealth, and Certificate of Need (CON) laws. The authorization of additional telehealth benefits pursuant to the BBA of 2018 incentivizes new ways for MA plans to cover beneficiary access to health care beginning in 2020. As a result, CMS has been examining its network adequacy standards overall to determine how contracted telehealth providers should be considered when evaluating the adequacy of an MA plan network. In order to expand access to MA plans where network development can be challenging, we are reducing the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties (Micro, Rural, and Counties with Extreme Access Considerations (CEAC) county type designations) from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards. Also, MA plans will be eligible to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers in the following provider specialty types: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/ OB/GYN, Endocrinology, and Infectious Diseases. Additionally, MA organizations may also receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state. We solicited

comments from stakeholders on various aspects of our proposal, which informed the network adequacy methodology adopted in this final rule.

g. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40)

Sections 1851(e)(4) and 1860D-1(b)(3) of the Act establish special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in, or disenrollment from, MA and Part D plans. The Secretary also has the authority to create SEPs for individuals who meet other exceptional conditions. We are codifying a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs provides transparency and stability to the MA and Part D programs by ensuring that these SEPs are known and changed only through additional rulemaking. Among the finalized SEPs are the SEP for Government Entity-Declared Disaster or Other Emergency, the SEP for Employer/Union Group Health Plan (EGHP) elections, and the SEP for Individuals Who Disenroll in Connection with a CMS Sanction. We are also establishing two additional SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

3. Summary of Costs and Benefits

Provision	Description	Impact
Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)	CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is removing the prohibition on beneficiaries with ESRD enrolling in an MA plan.	To estimate the impact, we used a pre-statute baseline. The analysis shows that removing the prohibition for ESRD beneficiaries to enroll in MA plans results in net costs to the Medicare Trust Funds ranging from \$23 million in 2021 to \$440 million in 2030.

Provision	Description	Impact
<p>Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)</p>	<p>CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is finalizing that MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Instead, Medicare FFS will cover the kidney acquisition costs for MA beneficiaries, effective 2021.</p>	<p>To estimate the impact, we used a pre-statute baseline. This analysis shows that FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from \$212 million in 2021 to \$981 million in 2030.</p>
<p>Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)</p>	<p>CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is removing costs for organ acquisitions for kidney transplants from the calculation of MA benchmarks and annual capitation rates.</p>	<p>To estimate the impact, we used a pre-statute baseline. This analysis shows that excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from \$594 million in 2021 to \$1,346 million in 2030.</p>
<p>Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)</p>	<p>CMS is finalizing an increase in the weight of patient experience/complaints and access measures. CMS is also finalizing the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points. However, the application of Tukey outlier deletion will be delayed until the 2024 Star Ratings.</p>	<p>Updating the patient experience/complaints and access measures weight creates a cost which is offset after the first year by using the Tukey outlier deletion. The net cost to the Medicare Trust Fund from the increased weight is \$345.1 million in 2024; the net savings from both the increased weight and Tukey outlier deletion will grow over time reaching \$999.4 million by 2030. The net reduction in spending to the Medicare Trust Fund through and including 2030 is \$4.1 billion.</p>

Provision	Description	Impact
<p>Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)</p>	<p>CMS is finalizing our three proposed amendments to the Medicare MLR regulations. (1) We will allow MA organizations to include in the MLR numerator as “incurred claims” all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of “provider” at § 422.2. (2) We also are codifying our definitions of partial, full, and non-credibility and credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296) for MA and Part D MLRs. (3) We are finalizing our proposal to apply a deductible factor to the MLR calculation for MA MSA contracts receiving a credibility adjustment. The deductible factor, which functions as a multiplier on the credibility adjustment factor, is calibrated so that the probability that a contract will fail to meet the MLR requirement is the same for all contracts that receive a credibility adjustment, regardless of the deductible level.</p>	<p>(1) Our change to the type of expenditures that can be included in “incurred claims” will have neutral dollar impact on the Medicare Trust Fund. These provisions will result in a transfer of funds from the Treasury, through the Medicare Trust Fund, to MA organizations. This transfer will take the form of a reduction in the remittance amounts withheld from MA capitated payments. The amount of this transfer is \$35 to \$55 million a year, resulting in plans obtaining \$455 million over 10 years.</p> <p>(2) Codifying the definitions of partial, full, and non-credibility and the credibility factors is unlikely to have any impact on the Medicare Trust Fund.</p> <p>(3) The deductible factor to the MLR calculation for MA MSA contracts is estimated to result in a gradually increasing cost to the Medicare Trust Fund of \$1 to \$6 million per year, arising from the Trust Fund paying for benefits due to expected increased enrollment, and will result in a \$40 million cost through, and including, 2030.</p>
<p>Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)</p>	<p>CMS is-- (1) strengthening network adequacy rules for MA and cost plans and to make them more transparent to plans by codifying our existing network adequacy methodology and standards, with some modifications; (2) allowing MA plans to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth providers; (3) allowing MA organizations to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state where CMS has not already customized the standards for that area; and (4) reducing the required percentage of beneficiaries residing within maximum time and distance standards in certain county types (Micro, Rural, and CEAC).</p>	<p>Changes to network standards are unlikely to have any impact on the Medicare Trust Fund.</p>

Provision	Description	Impact
Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40)	CMS is codifying a number of SEPs adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. CMS is also establishing two new SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.	This provision codifies existing practice since MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. Consequently, the provision will not have added impact.

B. Background

We received approximately 490 timely pieces of correspondence containing multiple comments on the provisions implemented within this final rule from the proposed rule titled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” which published February 18, 2020, in the **Federal Register** (85 FR 9002). Comments were submitted by MA health plans, Part D sponsors, MA and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, and other vendor and professional associations.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based the comments received. As noted previously, we intend to address the proposals from the February 2020 proposed rule that are not included in this final rule in subsequent rulemaking. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. For

example, we received comments about how much MA organizations pay network providers, and comments that recommend CMS adopt completely new Star Ratings measures or change HEDIS measures during the COVID-19 pandemic. CMS did not make any proposals in the February 2020 proposed rule on these topics, and as such, those out-of-scope public comments are not addressed in this final rule. However, we note that in this final rule we are not addressing comments received with respect to the other provisions of the February 2020 proposed rule that we are not finalizing at this time. Rather, we will address these comments in subsequent rulemaking, as appropriate.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

The BBA of 2018 (Pub. L. 115-123) was signed into law on February 9, 2018. The law included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans, specifically amending section 1852(a)(3) of the Act to add a new subparagraph (D) authorizing a new category of supplemental benefits that may be offered by MA plans. We discussed this new authority in the April 2018 final rule (83 FR 16481 through 16483).² We proposed to codify the existing guidance (April 2019 Health Plan Management System (HPMS) Memo³ and the 2020 Call Letter⁴) and parameters for these special supplemental benefits for chronically ill enrollees at § 422.102(f) to implement section 1852(a)(3)(D) of the Act.

Specifically, the BBA of 2018 amended section 1852(a)(3) of the Act to: (1) authorize MA plans to provide additional supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee to chronically ill enrollees; (2) permit those additional supplemental benefits to be not primarily health related; (3) define “chronically ill enrollee” to limit eligibility for these additional supplemental benefits; and (4) authorize CMS to waive uniformity requirements in connection with providing these benefits to eligible chronically ill enrollees. We refer to these benefits hereafter as Special Supplemental Benefits for the Chronically Ill (SSBCI). The heading for new subparagraph (D) of section 1852(a)(3) of the Act, as added by the BBA, states, “Expanding supplemental benefits to meet the needs of chronically ill enrollees.” Consistent with this text,

² <https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf>

³ https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf

⁴ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>

we interpret the intent of this new category of supplemental benefits as enabling MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill enrollee population.

Section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who--

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
- Has a high risk of hospitalization or other adverse health outcomes; and
- Requires intensive care coordination.

Thus, with respect to SSBCI benefits, at § 422.102(f)(1)(i), we proposed to codify this definition of a chronically ill enrollee. Section 1859(f)(9) of the Act requires us to convene a panel of clinical advisors to establish and update a list of conditions that meet the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act, which provides how having such a condition is an eligibility criterion for enrollment in a chronic care special needs plan. The standard for severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act is substantially similar to the criterion used in defining “chronically ill enrollee” for purposes of SSBCI eligibility. We proposed that MA plans may consider any enrollee with a condition identified on this list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. Further, an MA plan may consider any chronic condition not identified on this list if that condition is life threatening or significantly limits the overall health or function of the enrollee. We explained that our proposal was based on our policy goal of allowing MA plans the flexibility to continue to innovate around providing care

for their specific plan populations. This includes targeted chronic conditions. We stated that we recognize that there may be some conditions or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition (for purposes of the statutory definition of a chronically ill enrollee), but may not be present on the list. To encourage plans to identify needs within their unique plan population and to avoid preventing a plan from addressing a condition or need in their population that may not be on the list, we proposed regulation text permitting us to publish a non-exhaustive list of medically complex chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to be life threatening or significantly limit the overall health or function of an individual. This was proposed at § 422.102(f)(1)(i)(B).

As we explained in the proposed rule, we did not propose that MA plans be required to submit to CMS the processes used to identify chronically ill enrollees that meet the three pronged definition of chronically ill enrollee.

However, plans should describe the chronic conditions for which they will offer SSBCI in the notes field in the plan benefit package submitted to CMS. We emphasized that all three criteria must be met for an enrollee to be eligible for the SSBCI authorized under section 1852(a)(3)(D) of the Act. In subregulatory guidance (April 2019 HPMS Memo and the 2020 Call Letter), CMS noted that we expect MA plans to document their determinations about an enrollee's eligibility for SSBCI based on the statutory definition. We proposed to codify this as a requirement at § 422.102(f)(3)(ii). In addition, we also proposed at § 422.102(f)(3)(ii) to require plans to make information and documentation (for example, copies of the internal policies used to make the determinations, etc.) related to determining enrollee eligibility as a chronically ill enrollee available to CMS upon request.

We proposed a definition of SSBCI at paragraph (f)(1)(ii). In addition to limiting the class of enrollees who may be eligible to receive the new SSBCI benefits to the chronically ill, section 1852(a)(3)(D) of the Act requires that the specific supplemental benefit provided under this authority have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We proposed to codify this statutory requirement as part of the definition of SSBCI. Because SSBCI are supplemental benefits, they must also comply with the criteria for supplemental benefits that we proposed to codify at § 422.100(c)(2)(ii), which was discussed in detail in section VI.F. of the proposed rule. We are not addressing that proposal in this final rule and intend to address it in a future final rule. We considered whether the regulation for SSBCI should explicitly reference those requirements for supplemental benefits (proposed in § 422.100(c)(2)(ii)) to make this clear and solicited comment on this point.

Traditionally, CMS has required supplemental benefits to be benefits that: (1) are primarily health related; (2) require the MA plan to incur a non-zero medical cost; and (3) are not covered under Medicare Parts A, B or D. In light of the authority in section 1852(a)(3)(D) of the Act for SSBCI, we modified some aspects of this longstanding policy to address SSBCI. First, as the statute provides that SSBCI may be not primarily health related, we proposed specific text on this point in both §§ 422.100(c)(2)(ii) and 422.102(f)(1)(ii). Second, we proposed regulation text at § 422.100(c)(2)(ii)(B) that the requirement that the MA organization incur a non-zero direct medical cost for all supplemental benefits would mean, in the context of SSBCI that are not primarily health related, the MA organization must incur a non-zero direct non-administrative cost for the SSBCI. In all other respects not specifically addressed as part of our proposal, SSBCI would be treated like and subject to the same standards as other supplemental benefits. Although we are not finalizing the requirements for supplemental benefits proposed to be codified at §

422.100(c)(2) in this final rule, we are clarifying that our final rule for SSBCI at § 422.102(f) incorporates these concepts.

Under section 1852(a)(3)(D)(ii)(I) of the Act, SSBCI benefits may include items or services that are not primarily health related. As discussed in detail in section VI.F. of the proposed rule, a primarily health related benefit is an item or service that is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization.

Therefore, at § 422.102(f)(1)(ii), we proposed to codify, as part of the definition, that SSBCI benefits may be non-primarily health related SSBCI benefits. Our proposed regulation text included a cross-reference to the regulation text we proposed at § 422.100(c)(2)(ii) to codify the definition of primarily health related. In the proposed rule, we made clear that in all cases, an SSBCI must have, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee. By including it in the definition, we proposed to implement the statutory authority for MA plans to offer both primarily health and non-primarily health related SSBCI. We summarized in the proposed rule how the 2019 HPMS memo provided examples of what could be non-primarily health related SSBCI benefits, depending on the needs and health or overall function of the chronically ill enrollee. Those examples included: meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, indoor air quality and equipment and services, access to community or plan-sponsored programs and events to address enrollee social needs (such as non-fitness club memberships, community or social clubs, park passes, etc.), complementary therapies (offered alongside traditional medical treatment), services supporting self-direction, structural home modifications, and general supports for living (for example, plan-sponsored

housing consultations and/or subsidies for rent or assisted living communities or subsidies for utilities such as gas, electric, and water). We stated in the proposed rule that the 2019 HPMS memo this guidance was equally applicable to our proposed regulation and part of how we intended our proposed regulation to be implemented and enforced.

We explained in the proposed rule another way that the statutory authority for SSBCI to be not primarily health related would be part of our proposed regulation. Unlike with traditional supplemental benefits, MA plans might not incur direct medical costs in furnishing or covering SSBCI. In the CY 2020 Call Letter, we issued guidance that so long as an MA plan incurs a non-zero non-administrative cost in connection with SSBCI, the benefits would be considered to meet this standard. As supplemental benefits, SSBCI may also take the same form as traditional supplemental benefits. For example, reductions in cost sharing for benefits under the original Medicare fee-for-service program are an allowable supplemental benefit, as reflected in the definitions of mandatory supplemental benefit in § 422.2. Thus, we stated in the proposed rule that SSBCI can be in the form of—

- Reduced cost sharing for Medicare covered benefits (such as to improve utilization of high-value services that meet the definition of SSBCI);
- Reduced cost sharing for primarily health related supplemental benefits;
- Additional primarily health related supplemental benefits; or
- Additional non-primarily health related supplemental benefits.

Eligibility for SSBCI must be determined based on identifying the enrollee as a chronically ill enrollee, using the statutory definition, and if the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. In the April 2019 HPMS memo CMS clarified that MA plans can provide non-primarily health related

supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits maintain or improve the health or function of that chronically ill enrollee. MA plans may consider social determinants when determining eligibility for an SSBCI of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI. We proposed to codify (at § 422.102(f)(2)(iii)) the ability of an MA plan to consider social determinants (for example, food and housing insecurity) when determining whether an SSBCI benefit is likely to improve or maintain the health of a chronically ill enrollee,

We also explained how our proposal addressed the statutory authority to waive uniformity for an MA plan to offer SSBCI. Generally, § 422.100(d) and other regulations require all MA plan benefits to be offered uniformly to all enrollees residing in the service area of the plan. As explained in the April 2018 final rule (83 FR 16480 through 16485), MA plans may also provide access to services (or specific cost sharing or deductibles for specific benefits) that are tied to a disease state in a manner that ensures that similarly situated individuals are treated uniformly. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes CMS to waive the uniformity requirements generally applicable to benefits covered by MA plans with respect to SSBCI, effective in CY 2020. As discussed in the April 2018 final rule (83 FR 16481 and 16482), this gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform across the entire population of chronically ill enrollees in the MA plan and may vary SSBCI offered to the chronically ill as a specific SSBCI relates to the individual enrollee's specific medical condition and needs. We proposed to codify

the authority for this waiver at § 422.102(f)(2)(ii) such that upon approval by CMS, an MA plan may offer non-uniform SSBCI.

In both the CY 2020 Call Letter and the April 2019 HPMS memo, we explained how we expect MA plans to: (i) have written policies based on objective criteria (for example, health risk assessments, review of claims data, etc.) for determining SSBCI eligibility to receive a particular SSBCI benefit; (ii) document these criteria; and (iii) make this information available to CMS upon request. We also proposed to codify requirements at § 422.102(f)(3)(iii) and (iv) for MA plans that offer SSBCI to have written policies based on objective criteria, document those criteria, to document each determination that an enrollee is eligible to receive an SSBCI, and to make this information available to CMS upon request. We explained in the proposed rule that objective criteria are necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. We also proposed, at § 422.102(f)(3)(i), to require plans to have written policies for determining enrollee eligibility and to document its determination that an enrollee is a chronically ill enrollee based on the statutory definition codified in paragraph (f)(1)(i) of this section. We proposed to require plans to make information and documentation related to determining enrollee eligibility available to CMS upon request at § 422.102(f)(3)(ii). We explained in the proposed rule that the determination on the benefits an enrollee is entitled to receive under an MA plan's SSBCI is an organization determination that is subject to the requirements of part 422, subpart M, including the issuance of denial notices to enrollees.

We also explained how the proposal on SSBCI would codify already existing guidance and practices and therefore was not expected to have additional impact above current operating

expenses. We also stated our belief that our proposal would not impose any collection of information requirements.

We thank commenters for helping inform CMS' SSBCI policy. We received approximately 62 comments on this proposal; we summarize these comments and our responses as follows:

Comment: A number of commenters supported CMS' proposal to allow MA plans to consider any chronic condition not identified on chronic condition list if that condition is life threatening or significantly limits the overall health or function of the enrollee. A commenter encouraged CMS to continue requiring MA plans to consider any enrollee with a condition identified on list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.

Response: We thank commenters for their feedback. In the April 24, 2019 HPMS memo and 2020 Call Letter, CMS indicated that it would consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. This was done in an effort to maintain a consistent standard in CMS policy for what is a chronic condition (for purposes of eligibility for SSBCI and for special needs plans for individuals with a severe or disabling chronic condition).

In this rule, we proposed that MA plans may consider any enrollee with a condition identified on the list of chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to meet the statutory criterion of having one or more comorbid and medically

complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee in an effort to also maintain this consistency. However, we recognize that there may be some conditions and/or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition, but the chronic condition may not be present on the list of medically complex chronic conditions. Therefore, we also proposed that a plan may identify an enrollee as meeting this first criterion of the definition of chronically ill enrollee – that the enrollee have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee – using a condition that is not on that list so long as the statutory (and proposed regulatory) standards are met. As stated in the proposed rule, we want to allow plans the flexibility to identify needs within their unique plan population and do not want to inadvertently prevent a plan from addressing a condition or need in their population that may not be on the list. We wish to allow plans the flexibility to continue to innovate around providing care for their specific plan populations. Thus, we are finalizing this aspect of our proposal, which is reflected in how § 422.102(f)(1)(i)(B) provides that the list published by CMS is a non-exhaustive list. We reiterate that, as we proposed, we intend this list to be the list of severe or disabling chronic conditions developed by the panel of technical advisors convened in accordance with section 1859(f)(9)(A)(i) of the Act. In addition to having one or more comorbid and medically complex conditions that is life threatening or significantly limits overall health and function, an enrollee must also have a high risk of hospitalization and require intensive care coordination to be considered chronically ill. Additionally, the covered item or service must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Comment: Some commenters requested CMS provide additional guidance concerning the definition of the phrase “intensive care coordination” as it is used in the regulation.

Response: We expect MA plans to develop objective criteria (for example, health risk assessments, review of claims data, etc.) in determining SSBCI eligibility. We are not adopting a specific definition or standard for the statutory requirement that the chronically ill enrollee require intensive care coordination as the phrase is sufficiently clear for MA organizations to develop reasonable approaches in determining when it is met. We believe that objective criteria for determining what constitutes intensive care coordination are present in the medical community and readily accessible to the plan, such as the expertise of the plan medical director and plan physicians. We believe MA plans should have flexibility to determine what objective criteria to use when determining what meets the intensive care coordination criterion in their plan populations. However, we will keep this recommendation under advisement as we gain experience with SSBCI offerings.

Comment: A few commenters requested CMS allow plans to use functional status, rather than medical diagnoses, to determine whether an enrollee is eligible for SSBCI. A commenter stated that individuals with the same diagnosis may have different functional limitations and therefore different needs.

Response: We thank commenters for their feedback. We note that for the purposes of SSBCI, the statute requires the enrollee to have a chronic condition(s) that is life threatening or limits the overall health and function of an enrollee; this is in addition to the requirements that the enrollee have a high risk of hospitalization or other adverse health outcomes and require intensive care coordination to be eligible for SSBCI. Two of the required criteria refer to the

function of the enrollee, so we believe it is sufficiently clear that this is something that can be considered when determining if an enrollee is a chronically ill enrollee.

Once meeting the criteria to be a chronically ill enrollee, and therefore eligible for SSBCI, the statute and our implementing regulation permit SSBCI that are designed to address the functional status of the enrollee. As discussed in the proposed rule, SSBCI must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Thus, a plan may choose to provide an SSBCI that improves or maintains overall function of an enrollee who is eligible for SSBCI per the three-pronged definition.

Comment: Some commenters expressed concern that the new SSBCI policies could potentially undermine the role of SNPs in the Medicare Advantage program.

Response: SNPs are specifically designed to provide targeted care to special needs individuals. SNPs offer a wider array of specific interventions regarding their targeted population. Additionally, SNPs are required to develop and implement an evidence based model of care that provides structure for care management processes and systems that enables the plan to provide coordinated care for special needs individuals. We do not believe that the availability of SSBCI as permissible supplemental benefits undermines the specialized care model that SNPs provide. We believe that the MA program and the diverse needs of Medicare population have room for MA plans that are designed, as a whole, to address special needs populations and for specific benefits designed to improve or maintain the health or overall function of a specific chronically ill enrollee

Comment: Some commenters expressed concern that the new benefit flexibilities, including the different eligibility requirements, could confuse enrollees.

Response: MA plans are required to provide enrollees with information on covered benefits, including SSBCI if the MA plan offers them, each year through the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In addition, MA organizations must comply with the marketing and communications regulations in part 422, subpart V, when issuing any information regarding SSBCI to enrollees; these include prohibitions on MA organizations misleading beneficiaries, providing information that is inaccurate, or engaging in activities that confuse beneficiaries. Consistent with MCMG requirements, it is our expectation that plans communicate information on SSBCI to enrollees in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits.

Comment: Several commenters requested that CMS ensure that these new benefit flexibilities for the chronically ill do not lead to discrimination against high-need beneficiaries.

Response: We thank commenters for sharing their concerns. We note that section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. MA regulations (for example, §§ 422.100(f)(2) and 422.110(a)) reiterate and implement this non-discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans implement these benefit flexibilities for SSBCI, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.⁵ Additionally, CMS reviews benefit designs to make sure that the overall impact is

⁵ Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. Additionally, we believe it is important to note that in order to be eligible for SSBCI an enrollee must as stated above 1) have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee; 2) have a high risk of hospitalization or other adverse health outcomes; and 3) require intensive care coordination. It is only enrollees with chronic conditions, as described by the three pronged definition above, that are eligible for these benefits. Thus, it is these individuals who are intended to receive these special benefits.

Comment: Commenters also requested CMS provide additional subregulatory guidance on SSBCI and supplemental benefits in general, including updating Managed Care Manuals. Although characterized as being in response to the proposal to change the costs that may be included in the definition of “incurred costs” for MLR purposes (addressed in section V.I. of the proposed rule and section IV.D of this final rule), other commenters noted how SSBCI are not always delivered by medical providers.

Response: We believe that our discussion in the proposed rule explaining the proposal we are finalizing provides extensive guidance for MA organizations on this topic. The April 2019 HPMS Memo and CY 2020 Call Letter address SSBCI and that guidance is still applicable as § 422.102(f), as proposed and as finalized, codifies significant portions of that guidance. CMS will consider additional subregulatory guidance, including manual updates, as the program develops. Additionally, as discussed in the 2020 Call Letter, we note that MA plans may contract with community-based organizations such as those providing other home and community-based services (HCBS) to provide supplemental benefits, including SSBCI, that are compliant with the statutory and regulatory requirements. For example, an MA plan could elect to offer, as a SSBCI,

the provision of meals or food/produce and pay a community-based organization for furnishing the covered benefit. Community-based organizations can also help determine whether an individual meets the eligibility requirements for SSBCI. These organizations may already be providing services in the community and, in some cases, have contractual arrangements with Medicaid managed care or MA plans. We note that some community services programs are funded by the HHS Administration for Community Living (ACL) and utilizing ACL programs would also be permissible in delivering these supplemental benefits. This is consistent with the amendment to § 422.2420, discussed in section III.D.1 of this final rule, to include amounts paid for SSBCI to providers that are not necessarily healthcare professionals as incurred claims in the calculation of the MLR.

Comment: Some commenters requested CMS provide greater detail on allowable SSBCI including meals, transportation, and durable medical equipment (DME).

Response: A non-exhaustive list of examples of non-primarily health related, which includes meals (beyond a limited basis) and non-medical transportation SSBCI can be found in the April 2019 HPMS Memo and this preamble. However, we note the requirements around the SSBCI, which include the statutory authority for the Secretary to waive uniformity requirements and the statutory requirement that SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee,

allow significant of flexibility for MA plans to consider the needs of enrollees who meet the high standards in the definition of chronically ill enrollee and to design benefits to assist enrollees at an individualized level. We encourage MA plans to continue to consider the unique needs of their plan populations when proposing items or services that meet SSBCI conditions in their bid and submitted plan benefit package. As explained in the referenced April 2019 HPMS

memo, MA plans have broad discretion in developing items and services they may offer as SSBCI provided that the item or service has a *reasonable* expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Under our current guidance and this final rule, MA plans also have broad discretion in determining what may be considered ‘a reasonable expectation’ when choosing to offer specific items and services as SSBCI so long as the statutory standard is met.

Concerning DME, MA plans are required to “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Medicare Part A and Part B” (see 42 CFR 422.101(a)), which includes coverage of durable medical equipment, prosthetics and supplies. As discussed in the referenced HPMS memo, non-Medicare-covered safety devices to prevent injuries in the home or bathroom are considered primarily health related and may be offered as a supplemental benefit to all enrollees for whom the item is medically necessary. We remind MA organizations of our long-standing guidance in Chapter 4 of the Medicare Managed Care Manual about medical necessity in the context of supplemental benefits and how MA plans may develop their own medical necessity policies and procedures, so long as access to and coverage of Part A and Part B benefits is not more restrictive than Original Medicare. Other equipment that is not primarily health related may be considered as an SSBCI if it has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Comment: A few commenters suggested CMS allow plans to target some services to address social risk factors. A commenter suggested CMS test ways to provide more flexibility in targeting supplemental benefits to address social risk factors like homelessness.

Response: The statute does not authorize MA plans to offer and cover supplemental benefits, even SSBCI, based solely on social risk factors; the statute explicitly provides that eligibility for SSBCI is based on whether an enrollee meets the definition to be a chronically ill enrollee, which does not include a reference to social risk factors. As discussed in this preamble, MA plans can provide non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits have a reasonable expectation of maintaining or improving the health or function of that chronically ill enrollee. MA plans may consider social determinants of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, they may not use social risk factors as the sole basis for determining eligibility for SSBCI. Please note that the current CMS Innovation Center Medicare Advantage Value-Based Insurance Design (VBID) model allows participants to vary supplemental benefits based on chronic condition or socioeconomic status or a combination of the two. MA organizations have the option of participating in this model if they choose.

Comment: Some commenters suggested that information and documentation concerning SSBCI eligibility determinations should be reported more broadly, rather than only made available upon request. A commenter stated that this information would be necessary to better understand the efficacy of offered benefits.

Response: We thank commenters for their suggestions. At this time, we do not wish to place additional reporting burden on plans. However, we will take this comment under advisement as we continue to develop and refine SSBCI policy. Concerning the written policy requirements at § 422.102(f)(3)(i) and (iii), we clarify that these requirements concern the existence of such policies and that we do not intend to regularly review the content for

compliance with the substantive standards of the regulation. We are implementing the statutory authority for SSBCI in a way to provide discretion and flexibility for MA plans, consistent with our approach to supplemental benefits design, within the statutory and regulatory limits. Per § 422.102(f)(3)(i), plans are required to have written policies for determining enrollee eligibility. As we explained in the CY 2020 Call Letter, maintaining detailed internal documentation is, at a minimum, necessary to address potential beneficiary appeals and complaints. However, MA organizations will have discretion in developing these policies. Additionally, per § 422.102(f)(3)(iii), plans are required have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document the criteria. We do not intend to closely monitor or regularly request these documentation and reiterate that MA plans will have discretion in designing which items and services to offer as SSBCI and for which chronically ill enrollees to cover them, so long as the statutory and regulatory standards are met.

Comment: Some commenters expressed concern that SSBCI are not available to individuals enrolled in Original Medicare. Other commenters suggested CMS test a model that includes original Medicare enrollees.

Response: The Balanced Budget Act of 1997 (BBA) authorized CMS to contract with public or private organizations to offer a variety of health plan options for beneficiaries. Under section 1852(a)(3)(D), MA plans are authorized to offer supplemental benefits, including SSBCI. The MA program has historically authorized MA plans to offer some form of additional or supplemental benefits to MA enrollees. Medicare beneficiaries choose to elect either original Medicare or an MA health plan that may have supplemental benefits. Concerning additional

models, CMS appreciates this suggestion and will take it under consideration as we consider new Innovation Center models.

Comment: Several commenters suggested CMS study how many beneficiaries actually receive these benefits and not just how many are eligible for them in order to understand the actual impact of these new benefits.

Response: We appreciate this comment and will take this comment under consideration as we monitor how MA plans offer these benefits and continue to develop these policies.

We thank commenters for their feedback.

As discussed in this preamble, because SSBCI are supplemental benefits, they must also comply with our longstanding interpretation of the criteria for supplemental benefits; we also proposed to codify those criteria at § 422.100(c)(2)(ii), which was discussed in detail in section VI.F. of the proposed rule. We considered whether the regulation for SSBCI should explicitly reference the requirements in § 422.100(c)(2)(ii) to make this clear and solicited comment on this point. We received no comments on this specific subject.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 422.102(f) largely as proposed. We are finalizing slight revisions to the regulation text, to eliminate a reference to § 422.100(c)(2)(i) in paragraph (f)(1)(ii) which was tied to the proposal regarding § 422.100(c)(2) that is not being addressed in this final rule. We are also correcting a typographical error in paragraph (f)(2)(iii).

B. Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

Special needs plans (SNPs) are MA plans created by the MMA that are specifically designed to provide targeted care and limit enrollment to individuals with special needs. Under section 1859 of the Act, SNPs are able to restrict enrollment to: (1) institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a State Plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, there are 321 SNP contracts with 734 SNP plans that have at least 11 members, including all of the following:

- 480 dual eligible SNPs (D-SNPs).
- 125 institutional SNPs (I-SNPs).
- 129 chronic or disabling condition SNPs (C-SNPs).⁶

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in – (1) missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible individuals receive the full

⁶ Centers for Medicare & Medicaid Services. *SNP Comprehensive Report*. (July 2019) Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Special-Needs-Plan-SNP-Data.html>.

array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, and beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.⁷

D-SNPs are intended to integrate or coordinate care for this population more effectively than standard MA plans or the original Medicare fee-for-service program by focusing enrollment and care management on dually eligible individuals. As of July 2019, approximately 2.6 million dually eligible individuals (1 of every 5 dually eligible individuals) were enrolled in 480 D-SNPs.

As summarized in our proposed rule, federal statute and implementing regulations have established several requirements for D-SNPs in addition to those that apply to all MA plans to promote coordination of care, including health risk assessment (HRA) requirements as described in section 1859(f)(5)(A)(ii)(I) of the Act and at § 422.101(f)(1)(i), evidence-based models of care (MOCs) as described in section 1859(f)(5)(A)(i) of the Act and at § 422.101(f), and state Medicaid agency contracts as described in section 1859(f)(3)(D) of the Act and at § 422.107. The state Medicaid agency contracting requirement allows states to require greater integration of Medicare and Medicaid benefits from the D-SNPs in their markets.

⁷ See Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. “Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon”, *Medical Care Research and Review*, (November 15, 2017) 1-17. Retrieved from <http://journals.sagepub.com/doi/abs/10.1177/1077558717740206>; Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis*, prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from <https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis>; Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf; and Medicare Payment Advisory Committee. “Chapter 2, Care coordination programs for dual-eligible beneficiaries.” In *June 2012 Report to Congress: Medicare and Health Care Delivery System* (June 16, 2012). Retrieved from http://www.medpac.gov/docs/default-source/reports/jun12_entirereport.pdf?sfvrsn=0.

More recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D-SNPs, beginning in 2021, including minimum integration standards, coordination of the delivery of Medicare and Medicaid benefits, and unified appeals and grievance procedures for integrated D-SNPs, the last of which we implemented through regulation to apply to D-SNPs with exclusively aligned enrollment, termed “applicable integrated plans.” These requirements, along with clarifications to existing regulations, were codified in the April 2019 final rule (84 FR 15680 through 15844).

We discussed in the proposed rule and reiterate here the pattern of federal legislation, CMS rulemaking, and state use of D-SNP contracting requirements has incrementally created new requirements for D-SNPs that have generally promoted additional beneficiary protections, coordination of care, and integration of Medicare and Medicaid coverage for dually eligible individuals. While many of these requirements impose additional burdens for D-SNPs, they have not impeded enrollment growth in these plans. Total D-SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.⁸ Participation of MA organizations is robust, and most markets are stable and competitive.

In this final rule, we address the emergence of “D-SNP look-alike” plans that are a hindrance to meaningful implementation of statutory requirements for D-SNPs, particularly those connected with the BBA of 2018. As the Medicare Payment Advisory Commission (MedPAC) described in its June 2018 and 2019 reports to Congress and as summarized in the proposed rule, D-SNP look-alikes have levels of dual eligible enrollment that are virtually indistinguishable from those of D-SNPs and far above those of the typical MA plan.

⁸ Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (July 2010 & July 2019). Retrieved from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/Special-Needs-Plan-SNP-Data.html>.

As discussed in the proposed rule, we believe the low enrollment of non-dually eligible individuals in D-SNP look-alikes results from benefits and cost-sharing that, like the benefits and cost-sharing offered by D-SNPs, are designed to attract only dually eligible individuals. In contrast to non-SNP MA plans, both D-SNPs and D-SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost-sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. With such a benefit design, many D-SNP look-alikes technically require members to pay higher cost sharing for Parts A and B services than most MA plans require, which we believe dissuades most non-dually eligible Medicare beneficiaries from enrolling. However, because most dually eligible individuals are Qualified Medicare Beneficiaries (QMBs) who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, we believe they are not dissuaded from enrolling in these non-D-SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D-SNPs in terms of levels of dual eligible enrollment and benefits and cost-sharing design, D-SNP look-alikes are regulated as non-SNP MA plans and are not subject to the federal regulatory and state contracting requirements applicable to D-SNPs.

As summarized in the proposed rule, the proliferation and growth of D-SNP look-alikes raises concerns related to effective implementation of the BBA of 2018 requirements; meaningful integration of Medicare-and Medicaid programs via state Medicaid agency

contracting; care coordination through HRAs; evidence-based MOCs; and beneficiary confusion stemming from misleading marketing practices by brokers and agents that misrepresent to dually eligible individuals the characteristics of D-SNP look-alikes. We direct readers to the proposed rule, 85 FR 9018 through 9021, for a more detailed discussion of D-SNP look-alikes and their impact on implementation of D-SNP Medicare and Medicaid integration.

Under our authority to adopt standards implementing the Part C statute and to add contract terms in sections 1856(b) and 1857(e)(1) of the Act, we proposed establishing contracting standards at § 422.514 for MA organizations based on their projected dually eligible enrollment in plan bids or on the proportion of dually eligible enrollees actually enrolled in the MA plan. As discussed in the proposed rule, a high rate of enrollment by dually eligible individuals in a non-D-SNP would allow us to identify non-SNP MA plans that are intended to predominantly enroll dually eligible individuals (that is, D-SNP look-alikes). To prevent the undermining of the statutory and regulatory framework for D-SNPs, we proposed a new regulation precluding CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds specific enrollment thresholds (85 FR 9021-9025). We also proposed that the regulation apply in any state where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals.

As described in our proposal, we would not enter into or renew MA contracts for an MA plan for an upcoming plan year if that MA plan exceeds specific enrollment thresholds for dually eligible individuals. However, MA organizations with plans exceeding the enrollment threshold that also have approved D-SNPs for the following plan year would be permitted to transition dually eligible enrollees from D-SNP look-alikes to D-SNPs for which the individuals are

eligible. We proposed this transition process to minimize disruptions to beneficiary coverage and allow enrollees in these D-SNP look-alikes to benefit from the statutory and regulatory care coordination and Medicaid integration requirements. We describe the specific proposed changes to § 422.514 as follows.

We proposed changing the title of § 422.514 by removing the word “minimum” because the changes we proposed to § 422.514 reflect an additional type of enrollment requirement beyond the minimum enrollment requirements currently articulated in § 422.514. We also proposed changing the title of paragraph (a) from “Basic rule” to “Minimum enrollment rules” for clarity due to the proposed change to the scope of § 422.514.

We proposed adding a new paragraph (d) to establish new contract requirements related to dual eligible enrollment. The proposed requirement at paragraph (d) would apply for an MA plan that is not a special needs plan for special needs individuals as defined in § 422.2. We explained our rationale in depth for this approach in the proposed rule.

We proposed to limit the requirement at paragraph (d) to states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as Medicare-Medicaid Plans (MMPs). We proposed this limitation because it is only in such states that the implementation of D-SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D-SNPs or comparable managed care plans like MMPs, the D-SNP requirements have not had any relevance historically, as there are no plans contracted with the state to implement the D-SNP requirements or otherwise integrate Medicare and Medicaid services. Therefore, the operation of a D-SNP look-alike would not have any material impact on the full implementation of federal D-SNP requirements. In such states, the existence of D-SNP look-alikes is not impeding state or federal implementation of any requirements for

enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D-SNPs or comparable managed care plans like MMPs. We also noted the limited number of states – eight, as of July 2019 – with no D-SNPs. Therefore, we expressed our belief that it is not critical for our proposed requirements in paragraph (d) to apply in such states. We solicited comment on whether the absence of these data sharing and care coordination requirements for D-SNP look-alikes in states where they could continue to operate under our final rule disadvantages the dually eligible individuals in D-SNP look-alikes and whether we should extend the proposed requirement at paragraph (d) to all states.

We proposed new paragraphs (d)(1) and (2) that would require that CMS not enter into or renew a contract, for plan year 2022 or subsequent years, for an MA plan that is a non-SNP plan that either:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan’s total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX, or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX, unless the MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination.

We explained that using each enrollment scenario is necessary to ensure that both new D-SNP look-alikes are not offered and that current, or existing, D-SNP look-alikes are not continued. We proposed a threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan’s enrollment because it far exceeds the share of dually eligible individuals in any given market and, therefore, would not be the result for any plan that had not intended to achieve high

dually eligible enrollment. As detailed in the proposed rule, MedPAC data show that our proposed threshold would have minimal impact on total dually eligible enrollment in non-SNP MA plans.

As discussed in the proposed rule, we considered an alternative discussed by MedPAC in its June 2019 report to Congress for identifying traditional MA plans with predominantly dually eligible enrollment: setting the bar at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points. We also considered setting a lower threshold for dually eligible enrollment at a point between 50 percent and our 80 percent threshold. However, as explained in the proposed rule, we proposed an enrollment threshold of 80 percent or higher as an indicator that the plan is designed to attract disproportionate dually eligible enrollment because it aligns with MedPAC's 2019 research findings, provides a threshold that would be easier for MA organizations to determine prospectively, and would be operationally easier for CMS to implement. We solicited comment on these alternative enrollment thresholds.

Under our proposal for paragraph (d)(2), we proposed making the annual determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the plan's enrollment in January of the current year in order to make such evaluations and issue the necessary information to affected MA organizations sufficiently early in the year for MA organizations to have time to take the necessary steps to adjust other plan offerings before the point at which CMS would decline to renew the contract for an MA plan – which effectively (and as described later in this section) would result in the non-renewal (that is, termination) of the D-SNP look-alike plan benefit package. Proposed paragraph (d)(2) would also limit the prohibition to MA plans that have been active for one or more years and

with enrollment greater than 200 individuals at the time of CMS' determination under proposed paragraph (d)(2).

In paragraph (e), we proposed processes and procedures for transitioning individuals who are enrolled in a D-SNP look-alike to another MA-PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D-SNP look-alikes. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA-PD plan (or plans) offered by the same MA organization, as long as any such MA-PD plan meets certain proposed criteria. This proposed transition process would allow MA enrollees to be transitioned from one MA plan offered by an MA organization to another MA-PD plan (or plans) without having to fill out an election form or otherwise indicate their enrollment choice as typically required, but it would also permit the enrollee to make an affirmative choice for another MA plan of his or her choosing.

In proposed paragraph (e)(1), we specified that, for coverage effective January 1 of the next year, the MA organization could only transition individuals from the D-SNP look-alike that is not being renewed into one or more MA plans (including a D-SNP) if such individuals are eligible to enroll in the receiving plan(s) in accordance with §§ 422.50 through 422.53. Thus, the individual would have to reside in the service area of the new plan and otherwise meet eligibility requirements for it. The proposed transition process would allow, but not require, the MA organization to transition dually eligible enrollees from a D-SNP look-alike into one or more D-SNPs offered under the MA organization, or another MA organization that shares the same parent organization as the MA organization, and therefore allow enrollees to benefit not only

from continued coverage under the same parent organization but also from the care coordination and Medicaid benefit integration offered by a D-SNP.

We also proposed at paragraphs (e)(1)(i) through (iii) specific criteria for any MA plan to receive enrollment through this transition process to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year:

- Under proposed paragraph (e)(1)(i), we would allow a non-renewing D-SNP look-alike to transition enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. SNPs receiving transitioned enrollment would not be subject to this proposed limit on dual eligible enrollment. As described in the proposed rule, the percent of dually eligible individuals in the resulting total enrollment would have to be determined prospectively in order for us to make a timely decision on whether to allow for an MA organization to transition enrollment into a non-SNP MA plan or plans. Under proposed paragraph (e)(3), we would make such determination by adding the cohort of enrollees that the MA organization proposes to enroll into a different non-SNP plan to the April enrollment of the receiving plan and calculating the resulting percent of dually eligible enrollment. As discussed in the proposed rule, we would make this calculation for each non-SNP plan into which the MA organization proposes to transition enrollment in order to ensure that the enrollment transitions do not result in another non-SNP MA plan being treated as a D-SNP look-alike.

- Under proposed paragraph (e)(1)(ii), we would require that any plan receiving transitioned enrollment be an MA-PD plan as defined in § 422.2.

- Under proposed paragraph (e)(1)(iii), any MA plan receiving transitioned enrollment from a D-SNP look-alike would be required to have a combined Part C and D beneficiary premium of \$0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a).

As proposed in paragraph (e)(2)(ii), the MA organization would be required to describe changes to MA-PD benefits and provide information about the MA-PD plan into which the individual is enrolled in the Annual Notice of Change (ANOC) that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees would receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period (AEP).

As proposed in paragraph (e)(4), in cases where an MA organization does not transition some or all current enrollees from a D-SNP look-alike plan to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), it would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2).

As discussed in more detail in the proposed rule preamble, this proposed transition process is conceptually similar to "crosswalk exception" procedures historically allowed by CMS and proposed at § 422.530 in the notice of proposed rulemaking. However, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities offered by MA organizations under the same parent organization, as well as between non-SNP plans and SNPs. Because this transition process is not the same as the crosswalk process, we proposed to codify it as part of § 422.514.

In the proposed rule, we explained how we also considered an alternative that would require transitioning any dually eligible individuals into a D-SNP for which they were eligible if such a plan is offered by the MA organization. In addition, we solicited comment on whether additional criteria for the receiving plan are necessary to protect beneficiaries who are affected by this proposed prohibition on renewing MA plans that meet the criteria in proposed § 422.514(d).

We described in the proposed rule our intent for the transition process to take effect in time for D-SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. This will allow current MA-PD plans that expect to meet the enrollment threshold in proposed paragraph (d)(2) to retain some or all of their current enrollment by transitioning these individuals to other MA-PD plans offered by the same MA organization a year before CMS implements any contracting limitations under this proposal.

Overall, our proposed rule focused on dually eligible individuals as a percentage of an MA plan's total enrollment. We considered using alternative criteria instead of, or in addition to, the percentage of projected or actual dually eligible enrollment, to identify non-SNP MA plans designed to exclusively or predominantly enroll dually eligible individuals. In particular, we considered identifying D-SNP look-alikes by the benefit design these plans typically offer — relatively high Parts A and B cost sharing and a high Part D deductible that make the plans unattractive to Medicare-only beneficiaries, supplemental benefits like dental and hearing services and over-the-counter drugs that mimic typical D-SNP offerings, and a premium for Part D coverage that is fully covered by the Part D low-income subsidy. We also considered using the percentage of MA rebate dollars allocated to buy down Parts A and B cost sharing compared to other supplemental benefits—D-SNP look-alikes typically allocate a greater percentage to the

latter—as a way to identify D-SNP look-alikes. We explained in the proposed rule why we did not propose those alternatives but solicited comment on whether these alternative criteria should be used instead of, or in addition to, the criteria for identifying D-SNP look-alikes and applying contracting prohibition.

We received the following comments on these proposed contract requirements and respond to them below:

Comment: Many commenters expressed strong support for our proposal to preclude CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds a specific threshold. Several commenters agreed with CMS that D-SNP look-alikes are an impediment to Medicare-Medicaid integration and meaningful implementation of federal and state requirements, including the new statutory requirements for D-SNPs under the BBA of 2018. A commenter appreciated that the proposal would, in most states, ensure that any entity whose enrollment consists mainly of dually eligible individuals follows the standards Congress established for MA plans serving dually eligible individuals. Several commenters agreed with MedPAC's 2018 and 2019 analyses, cited by CMS in the proposed rule preamble, that the proliferation of D-SNP look-alikes negatively impacts integrated care programs for dually eligible individuals. Some commenters believed the proposal would ultimately improve access to integrated care for dually eligible individuals. Several commenters also believed that D-SNPs were in the best position to serve the dually eligible population because of the D-SNP MOC, including care coordination and case management, which is not required of D-SNP look-alikes.

Several commenters also supported the proposed regulation because of their concern about how D-SNP look-alikes operate. A number of commenters expressed concern about D-

SNP look-alikes marketing to dually eligible individuals in ways that misrepresent the plans' ability to integrate Medicare and Medicaid services. Several commenters noted that while D-SNP look-alikes advertise that they integrate care, they are not designed to serve the needs of dually eligible individuals nor required to do so. For these reasons, many commenters believed look-alikes confuse dually eligible individuals about their coverage options and lead to beneficiary harm.

Response: We appreciate the widespread support we received for our proposal. Many of the commenters' concerns about D-SNP look-alikes mirror the comments discussed in the 2020 Final Call Letter⁹ and summarized in the proposed rule preamble. We believe that the contracting requirement we are finalizing in this rule will address these concerns and ensure the meaningful implementation of the new Medicare-Medicaid integration requirements under the BBA of 2018, along with other state and federal requirements. As discussed in the proposed rule and our responses to other comments, the prohibition will not apply to D-SNP look-alikes in states where there is a D-SNP or plan authorized by CMS to exclusively enroll dually eligible individuals.

Comment: A few commenters expressed support for CMS' efforts to integrate care but had concerns about the proposed contracting standard. Some commenters noted that the proposed rule may disrupt services and benefits for beneficiaries enrolled in D-SNP look-alikes. These commenters cautioned CMS to attend to continuity of care, the nuances of state requirements, and market dynamics as this final rule is implemented.

Response: We thank these commenters for their comments. We believe that the requirements we are finalizing in this rule, described in more detail later in this section, strike a balance between allowing for continuity of care for beneficiaries and promoting integrated care.

⁹ Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>.

In particular, as discussed later in this section, we are delaying implementation of D-SNP look-alike contract limitations for one additional year to provide sufficient time for MA organizations to develop and seek approval for new plans, coordinate with state integrated care efforts, and facilitate a transparent and smooth transition of beneficiaries. With a technical clarification described later in this section, we are finalizing our proposed transition approach for D-SNP look-alikes to transition enrollees into an MA plan or plans meeting certain criteria within the same parent organization to promote continuity of care.

Comment: Several commenters opposed our proposal to limit enrollment of dually eligible individuals in non-SNP MA plans. Some commenters noted that D-SNP look-alikes were created in response to states' contracting policies like those of California that restricted D-SNPs. A commenter questioned the need to regulate D-SNP look-alikes, citing the June 2019 MedPAC finding that only a small portion of traditional MA plans have dual eligible enrollment that comprises 80 percent or more of total plan membership.¹⁰

Some commenters believed that our proposal limited competition between MA plans that could lead to higher quality, innovative care, additional supplemental benefits, and improved provider network access for dually eligible individuals. A commenter stated that competition from D-SNP look-alikes targeted by our proposal has not hurt D-SNPs, noting that total D-SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.

A few commenters believed that D-SNP look-alikes fill critical gaps in markets where D-SNPs and MMPs are not available. Some commenters also believed that D-SNP look-alikes provide access to supplemental benefits and increased levels of care management, particularly for partial-benefit dually eligible individuals. These commenters were concerned that if the

¹⁰ See *June 2019 MedPAC Report to Congress, Chapter 12* at http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.

proposed contracting standard was implemented, D-SNP look-alike enrollees would lose access to these benefits and may return to the original Medicare fee-for-service program, which does not coordinate with Medicaid. A few commenters requested that, prior to finalizing any rule on D-SNP look-alikes, CMS perform a more detailed analysis of available options and impacts of the proposal on enrollees, both full- and partial-benefit dually eligible individuals, such as loss of benefits.

Several commenters expressed concern that CMS' proposed contracting standard would unnecessarily limit beneficiary choice. A few commenters requested that CMS explain how the value of choice was taken into account for this proposal. Other commenters encouraged CMS to continue to promote consumer choice and provide dually eligible beneficiaries with an array of plan options that allow individuals to choose how to best meet their health care needs. A commenter noted that the need for beneficiary choice was supported by the June 2018 MedPAC finding that 64 percent of partial-benefit dually eligible MA enrollees were enrolled in traditional MA plans in 2016,¹¹ and that a large percentage of full-benefit dually eligible individuals passively enrolled in MMPs also have indicated a preference for choice by opting out of MMP enrollment.

Response: We thank the commenters for the feedback on our proposal. We maintain that MA plans with enrollment exclusively, or predominantly, consisting of dually eligible individuals—the principal criterion that distinguishes D-SNPs from other MA plans in statute—should be subject to the federal regulatory and state contracting requirements that are applicable to D-SNPs. We note that, despite D-SNP regulations promulgated since 2006, MA organization participation in the D-SNP program is robust. Most D-SNP enrollment is in markets that feature

¹¹ See *June 2018 MedPAC Report to Congress, Chapter 9* at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

numerous other plan choices for beneficiaries, and enrollment in D-SNPs has continued to increase. We also note that while state contracting policies may have been the impetus for some sponsors to create D-SNP look-alikes, states are authorized to play a role in coordinating Medicaid benefits with MA plans that exclusively enroll dually eligible individuals, as described in section 164 of MIPPA, which amended section 1859(f) of the Act. Therefore, if our proposal leads to any change in the degree of beneficiary choice, such impact would be marginal, and we believe the benefits from our proposal – described here and in the proposed rule – outweigh any such impact.

We agree with the commenter that D-SNP look-alikes are currently a small number of all MA plans; however, D-SNP look-alikes’ growth – both in terms of the number of plans offered and their total enrollment – is concerning, especially given Congress’ requirements in the BBA of 2018 to further integrate Medicare and Medicaid benefits through D-SNPs. As noted in our proposed rule preamble, MedPAC found that D-SNP look-alike enrollment in California markets grew from around 5,000 in 2013 to over 95,000 in 2017.¹² MedPAC also explored enrollment trends more broadly, identifying 31 non-SNP plans¹³ operating in 2017 in which dually eligible individuals comprised 80 percent or more of total plan enrollment. These 31 plans, which operated in 10 states, included approximately 151,000 enrollees. MedPAC estimated that in 2019 enrollment would increase to 193,000 beneficiaries in 54 D-SNP look-alikes across 13 states.¹⁴

We acknowledge the commenters’ concerns about reducing access to supplemental benefits for D-SNP look-alike members and beneficiary choice, particularly for partial-benefit

¹² See *June 2018 MedPAC Report to Congress, Chapter 9* at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.

¹³ MedPAC also excluded employer group waiver plans (EGWPs) and a select group of medical savings account (MSA) plans.

¹⁴ See *June 2018 MedPAC Report to Congress, Chapter 9* at http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0 and *June 2019 MedPAC Report to Congress, Chapter 12* at http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.

dually eligible individuals. However, as we stated in the proposed rule, we chose not to propose regulating benefit design to avoid inadvertently diminishing benefit flexibility that genuinely improves competition and beneficiary choice. We also note that most D-SNP look-alike enrollment is in markets that feature numerous other plan choices for beneficiaries, including D-SNPs that offer similar benefits; therefore, D-SNP look-alikes are not generally filling gaps in most of their markets nor significantly contributing to beneficiary choice. The majority of D-SNP look-alikes will be able to transition enrollees into another MA plan under the process described at § 422.514(e) of this final rule; therefore, we project that few D-SNP look-alike enrollees will be enrolled by default in the original Medicare fee-for-service program when this regulation limits the continued offering of a D-SNP look-alike.

We also note the contracting standard that we proposed and are finalizing does not apply to MA plans in states without D-SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, further limiting the impact of this provision on access to supplemental benefits or beneficiary choice. Of the seven states that do not contract with D-SNPs or other plans authorized to exclusively enroll dually eligible individuals, only two have D-SNP look-alikes. As discussed in response to other comments on this topic, we will continue to engage with stakeholders to identify issues related to choice and access to supplemental benefits.

Comment: A commenter suggested that CMS work with states to provide multiple integrated care options for dually eligible individuals as an alternative to limiting D-SNP look-alikes. Another commenter requested that if CMS decides to implement the proposal, we should also require states to contract with D-SNPs.

Response: We note that section 164(c)(4) of MIPPA does not in any way obligate states to contract with a D-SNP; therefore, CMS does not have the authority to mandate states to

contract with D-SNPs, and states have significant control over the availability of D-SNPs. We generally agree that increasing the number of integrated care options for dually eligible individuals is desirable, and CMS will continue to work with states to identify ways to integrate Medicare and Medicaid benefits in a way that best serves the states' dually eligible population. We also provide technical assistance to states on integration issues, including through the Integrated Care Resource Center (see <https://www.integratedcareresourcecenter.com/>).

Comment: Several commenters supported our proposed approach in paragraph (d) to limit the availability of D-SNP look-alikes only in those states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. These commenters stated that look-alikes provide valuable supplemental benefits to dually eligible individuals that would not be available in a traditional MA benefit design in those states without D-SNP or MMP options. Some commenters further agreed with our rationale in the proposed rule that, in states without D-SNPs or comparable managed care plans (like MMPs), the existence of D-SNP look-alikes is not impeding full implementation of D-SNP integration requirements. A number of commenters recommended that our proposal to limit availability of D-SNP look-alikes apply only in counties where there are no D-SNPs or other plans authorized to exclusively enroll dually eligible individuals. A commenter agreed with CMS' observation that operating MA plans in rural areas presents a challenge to MA plan operations, including for D-SNPs. This commenter stated that, in those rural areas without D-SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, eliminating MA plan options can harm rather than benefit dually eligible individuals, and in the absence of integrated plan options, access to D-SNP look-alikes should be preserved.

Response: We appreciate these commenters' support of the proposed limit on this policy to states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as an MMP. In our proposed rule we noted that, as of July 2019, seven states did not have D-SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals. In these states, there are no plans contracted with the state to implement the D-SNP requirements or otherwise integrate Medicare and Medicaid services, and therefore the operation of a D-SNP look-alike would not have any immediate material impact on the full implementation of federal D-SNP requirements. In such states, the existence of D-SNP look-alikes is not impeding federal or state implementation of any requirements for enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D-SNPs or comparable managed care plans like MMPs.

We disagree with the recommendation to further limit the proposed D-SNP look-alike policy to those counties where a D-SNP or comparable managed care plan like an MMP currently exists. From our work with states on Medicare-Medicaid integration, we recognize that states often proceed incrementally, contracting first for integrated managed care plans in certain counties before incorporating more areas or going statewide. We believe that allowing D-SNP look-alikes to precede D-SNPs or other more integrated plans in these markets would hinder expansion of state efforts to expand integrated managed care. In addition, we believe it would be more complicated for CMS to administer, MA organizations to comply with, and consumers to understand, if there was a county-by-county limitation on D-SNP look-alike availability.

With respect to the comments about contracting in rural areas, we understand that operating MA plans, including D-SNPs, can be a challenge in areas where the Medicare

population is sparse and establishing networks is difficult. As discussed in section V.A. of this preamble, we are taking steps to improve access to managed care in rural areas through changes in network adequacy assessments. We will continue to monitor the volume of MA plans, including D-SNPs, offered in rural areas.

Comment: A commenter requested that CMS exempt from our proposed dual eligible enrollment rules in paragraph (d) D-SNP look-alikes in states that require the parent organization of the D-SNP to have a Medicaid contract with the state. The commenter expressed concern that implementing the rule as proposed would have an anticompetitive effect of locking out new plan entrants in such states.

Response: We disagree with the commenter that implementing paragraph (d) as proposed would reduce competition by not allowing new plan entrants in those states that limit D-SNP approval to parent organizations that have existing Medicaid contracts. As discussed in our April 2019 final rule in implementing the BBA of 2018, we sought to maintain existing state flexibility to promote integrated care for dually eligible individuals. As discussed earlier in this section, section 164 of MIPPA, which amended section 1859(f)(3)(D) of the Act, does not mandate that states contract with D-SNPs. The ability of states to determine the entities with which they enter into D-SNP contracts has been a core tenet for coordinating care between Medicare and Medicaid. We support efforts by states to further the integration of care coordination continuum and believe that the benefit from such coordination, in fact, increases competition to develop and win integrated products (that is, Medicaid contracts).

Comment: Many commenters stated that the dual eligible enrollment requirement should apply in all states to discourage the proliferation of plans that are not truly integrated and that offer limited or no care coordination. Several commenters noted that D-SNP look-alikes may

detract from state efforts to coordinate care for dually eligible individuals, such as managed fee-for-service models. These commenters believed that states that do not contract with D-SNPs or MMPs should be able to exercise oversight and have freedom to set a broader strategy to coordinate care for their dually eligible population without worrying about the proliferation of D-SNP look-alike products. A commenter stated that proliferation of D-SNP look-alikes may discourage states from future contracting with D-SNPs and gives plans no incentive to introduce D-SNPs. This commenter noted that CMS and states need to work together to improve the way they serve dually eligible individuals because such individuals include the highest need, highest cost Medicare and Medicaid beneficiaries, and limiting D-SNP look-alike regulation to only some states impedes progress toward that end.

Response: We appreciate the commenters' perspective on this issue. We believe that our proposal as finalized strikes a balance between prohibiting look-alikes and allowing them to continue in states without D-SNPs or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX. We do not believe that in such states, the existence of look-alikes is materially impeding state or federal implementation of any requirements for enhanced care coordination and Medicaid integration or providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D-SNPs or comparable managed care plans like MMPs. We recognize that substantial enrollment in D-SNP look-alikes in these states can alter the landscape if any of these states decides to begin contracting with D-SNPs. However, we believe state policy can accommodate these changes, for example, by contracting with MA organizations offering look-alikes to offer D-SNPs, enabling the transition of look-alike enrollees into more integrated plans. We continue to collaborate and work with all states to strengthen integrated care, and we will

monitor the penetration of MA plans as we continue to promote integrated care. As discussed in our proposed rule, we believe the limitation on the states where the dual eligible enrollment requirement applies will continue to protect states' ability to contract with plans – including for Medicaid behavioral health services and long-term supports and services (LTSS) – in a manner that promotes integration and coordination of benefits and a more seamless experience for dually eligible individuals in such plans. Therefore, in this final rule, we decline to expand our dual eligible enrollment requirements to plans operating in such states. However, we will continue to monitor D-SNP look-alikes in these states and consult with state officials about their impact on dually eligible individuals and state policy objectives.

Comment: Many commenters requested that CMS clarify whether the proposed 80 percent threshold for dual eligible enrollment in a non-SNP plan included both individuals entitled to full Medicaid benefits and individuals entitled to partial Medicaid benefits, such as state payment of Medicare Part B premiums or payment of Medicare premiums and cost sharing.

Response: Our proposed regulatory language in paragraph (d) regarding “enrollees who are entitled to medical assistance under a state plan under title XIX” is the same language used in section 1859(b)(6)(B)(ii) of the Act and in § 422.2 to define the population of special needs individuals D-SNPs may exclusively enroll. This language includes both full- and partial-benefit dually eligible individuals. Therefore, we clarify here that our proposed threshold for dual eligible enrollment – which we are finalizing in this rule – included both full- and partial-benefit dually eligible individuals.

Comment: A commenter recommended that our regulatory language in paragraph (d) be modified to refer to individuals who are “entitled to and enrolled in medical assistance,” since

plans only know which enrollees actually receive Medicaid benefits, not those whose income levels might qualify them for such benefits.

Response: While we appreciate the commenter’s concern, we believe that the language in § 422.514(d)(1) (individuals “entitled to medical assistance” under a state plan under Title XIX) sufficiently refers to individuals who have been determined to be entitled to medical assistance by virtue of having been enrolled in medical assistance under a state plan under Title XIX. That is our intent and interpretation of this language in § 422.514(d).

Comment: Some commenters recommended that the final rule not count any partial-benefit dually eligible individuals toward the threshold, while maintaining the threshold at 80 percent, in order to minimize the potential disruption caused by the non-renewal of D-SNP look-alikes, including D-SNP look-alikes in contracts with high Star Ratings. Other commenters supported setting the threshold at 80 percent if it applied only to full-benefit dually eligible individuals. Some commenters recommended that the threshold consist only of the categories of dually eligible individuals who were allowed to enroll in a D-SNP in any given market, defined at either the state or county level.

In contrast, other commenters supported counting enrollment of partial-benefit dually eligible individuals toward the 80 percent threshold. A commenter wrote that exclusion of partial-benefit dually eligible individuals while maintaining the threshold at 80 percent would drastically reduce the number of D-SNP look-alikes captured by the proposed regulation and potentially render the entire proposal “meaningless.”

Response: We disagree with the recommendation to exclude partial-benefit dually eligible individuals from the enrollment threshold and agree with those commenters who believed such an exclusion would render the proposal less effective. Such an exclusion would

allow 32 of the 64 non-SNP MA plans with more than 80 percent enrollment by both full- and partial-benefit dually eligible individuals to continue to operate. These include nine D-SNP look-alikes in states that have D-SNPs or MMPs that only enroll full-benefit dual eligible individuals. Those nine plans would continue to operate if, as suggested by a commenter, we did not count partial-benefit dually eligible individuals towards the threshold only in states that exclude these individuals from D-SNPs and other integrated plans. While partial-benefit dually eligible individuals are not currently eligible to enroll in D-SNPs or MMPs in those states, they have access to other MA plans that are not D-SNP look-alikes. As discussed in the proposed rule, over 98 percent of dually eligible individuals who are enrolled in non-SNP MA plans are in plans that are not D-SNP look-alikes.

The data show that the exclusion of partial-benefit dually eligible individuals would render the proposed regulation ineffective in achieving its primary goal: preserving the ability of CMS and states to meaningfully implement the BBA of 2018 requirements and to use D-SNPs and other integrated care plans to integrate Medicare and Medicaid for dually eligible individuals.

In addition, exclusion of partial-benefit dually eligible individuals from the threshold would allow any MA organization to design a benefit package and target enrollment for an MA plan that exclusively enrolled partial-benefit dually eligible individuals. Section 1859(b)(6)(B)(ii) of the Act, however, only allows D-SNPs to exclusively enroll dually eligible individuals.

Comment: Some commenters recommended excluding partial-benefit dually eligible individuals from the threshold and put forward a number of rationales for their recommendation. Some commenters stated that partial-benefit dually eligible individuals did not benefit from the

coordination of Medicaid benefits provided by D-SNPs or other integrated plans because they were not entitled to receive such benefits. A few commenters also noted that many states exclude partial-benefit dually eligible individuals from D-SNPs or other integrated plans, and therefore excluding partial-benefit dually eligible individuals from the enrollment threshold would ensure the availability of another meaningful plan option to such individuals. A few commenters noted that partial-benefit dually eligible individuals have greater social, functional, and health needs than the broader Medicare population and could benefit from the enhanced care coordination provided by MA plans, including the D-SNP look-alike in which they enrolled. Another commenter requested that CMS provide an analysis of how the proposed regulation would impact areas where partial-benefit dually eligible individuals are not allowed to enroll in D-SNPs or other integrated care options. A commenter that supported inclusion of partial-benefit dually eligible individuals in the 80 percent threshold stated that any CMS decision to exclude such individuals should be accompanied by a reduction in the threshold to capture roughly the same number of D-SNP look-alikes.

Response: We do not find these commenters' arguments persuasive. First, partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D-SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these individuals have greater social, functional, and health needs. States, through their contracts with D-SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D-SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the state.

Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

Of course, partial-benefit dually eligible individuals cannot benefit from these features of the D-SNP program if the state D-SNP contract excludes these individuals from enrollment, and we recognize that some states using managed care as a platform for integration exclude partial-benefit dually eligible individuals from D-SNPs and other managed care plans. While some states that are using the D-SNP platform for integration only allow full-benefit dually eligible individuals to enroll in D-SNPs, others allow partial-benefit dually eligible individuals to enroll in separate D-SNP plan benefit packages, facilitating integrated care and seamless provision of benefits for both categories of dually eligible individuals. We think that allowing D-SNP look-alikes to continue to enroll partial-benefit dually eligible individuals with no limit would discourage states from taking this approach.

Comment: A number of commenters recommended that we set a lower threshold for the percentage of dually eligible enrollees a non-SNP MA plan could have, either in actual or projected enrollment. These commenters expressed concern that a threshold of 80 percent could be “gamed” by MA organizations to keep their dual eligible enrollment just under the ceiling. Some commenters recommended that CMS set the ceiling for dual eligible enrollment at 50 percent, with a commenter citing MACPAC analysis showing faster growth in projected enrollment among MA plans with dual eligible enrollment greater than 50 percent than among those greater than 80 percent. Another commenter recommended a threshold of 60 percent.

Response: We appreciate the concern that CMS establish a threshold that is effective at curtailing D-SNP look-alikes, which we believe threaten to undermine our ability and that of our state partners to implement the higher integration standards under the BBA of 2018. However, as

described in the proposed rule, we believe our proposed 80 percent threshold is reasonable because it far exceeds the share of dually eligible individuals in any given market—no market has more than 50 percent dually eligible beneficiaries¹⁵—and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. The 80 percent threshold also captures almost three-quarters of enrollment in non-SNP plans with more than 50 percent dually eligible enrollees. We will monitor for potential gaming after implementation of this final rule by reviewing plan enrollment data, including the Monthly Membership Report, and consider future rulemaking as needed.

Comment: A range of commenters, including MACPAC and MedPAC, supported the proposed 80 percent threshold for projected and actual enrollment. Along with several other commenters, MACPAC and MedPAC urged CMS to monitor levels of MA dual eligible enrollment after implementation to verify that the final rule’s requirements remain effective against the proliferation of D-SNP look-alikes.

Response: We thank the commenters for their support and agree that post-implementation monitoring will be important to determine the effectiveness of the rule. We are finalizing the proposed regulatory language regarding the dual eligible enrollment threshold at paragraphs (d)(1)(ii) and (d)(2)(ii) of this final rule and reiterating here that the threshold includes enrollment of all categories of dually eligible individuals, including partial-benefit and full-benefit dually eligible individuals who are actually enrolled in medical assistance under a state plan under Title XIX.

Comment: A commenter requested that we clarify that the 80 percent threshold applies at the plan level (that is, the PBP level) and not at the contract, or “H number,” level.

¹⁵ *June 2019 MedPAC Report to Congress, Chapter 12* at http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.

Response: We reiterate here that the 80 percent threshold in paragraphs (d)(1)(ii) and (d)(2)(ii) applies at the plan level and not at the contract, or “H number,” level.

Comment: A commenter requested that we specify the data source used to determine the percentage of dually eligible enrollees in a plan subject to the proposed regulation.

Response: We intend to use data and reports on January enrollment and dual eligible status, such as the January Monthly Membership Report, generated by the MARx system (or a similar or successor report) to determine the percentage of dually eligible enrollees.

Comment: Several commenters stated that our proposed regulatory language at § 422.514(d), “CMS does not enter into or renew a contract under this subpart for an MA plan,” was confusing since the language references both contracts and plans. These commenters suggested that CMS clarify that it will not approve or renew a specific plan benefit package (PBP), rather than the entire contract, when D-SNP look-alike MA plans meet the 80 percent threshold.

Response: We appreciate the commenters’ request for clarification. When an MA organization enters into a contract with CMS to offer MA products, the MA organization can establish multiple PBPs within that one contract, so long as those products are the same type (for example, all HMO or all PPO). We proposed the language at paragraph (d) to accommodate this reality. When an MA organization has multiple plans under one contract, § 422.514(d), read in combination with contract severability rules at § 422.503(e), allows CMS to sever the D-SNP look-alike from the rest of the contract, in effect allowing CMS to renew only the portion of the contract that does not include the D-SNP look-alike. We believe the language at paragraph (d) accurately describes our intent. Therefore, we are finalizing this regulatory language as proposed. In addition, for those circumstances where the D-SNP look-alike is the only PBP

offered in the contract, we are finalizing a new paragraph (f) to clarify that we would consider actions taken consistent with paragraph (d) to warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion pursuant to §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2). In other words, when CMS declines to enter into or renew a contract consistent with paragraph (d), that action does not preclude the impacted MA organizations from applying for a new MA contract or a service area expansion or its board members or trustees from serving another MA organization.

Comment: A commenter recommended that CMS consider defining D-SNP look-alikes as MA organizations that offer a D-SNP and an MA-PD plan under the same contract, with the majority (that is, 50 percent or more) of dually eligible beneficiaries enrolled in the MA-PD plan rather than the D-SNP.

Response: While we appreciate the comment, we do not understand the rationale for defining D-SNP look-alikes as MA organizations that have a majority of dually eligible individuals enrolled in an MA-PD plan as compared to a D-SNP offered by the same MA organization. We would be concerned that any such policy would undermine our proposal in two ways. First, it would permit certain organizations to maintain D-SNP look-alikes whenever such plans were coupled with D-SNPs with a larger number of dually eligible individuals, even if the D-SNP is in a different geographic area. Second, it would allow D-SNP look-alikes to continue operating as long as the MA organization did not also offer a D-SNP under the same contract. Therefore, we decline to accept this recommendation.

Comment: A commenter supported CMS' proposal at § 422.514(d)(2) to exempt from the prohibition on D-SNP look-alikes those MA plans that are active for less than one year and

with enrollment less than or equal to 200 enrollees at the time of CMS' determination. A few commenters suggested that CMS consider alternative criteria for which new MA plans are exempted from our proposed requirements. A commenter recommended that CMS expand the exemption to plans that had been active three or more years. The commenter believed this change would allow plans to appropriately respond to any unexpected enrollment patterns. Another commenter encouraged CMS to raise the enrollment minimum from 200 enrollees to 500 enrollees to better align with enrollment levels already required for plan viability for Medicare Part D Prescription Drug Plans (PDPs) and reduce administrative burden.

Response: We appreciate the comments, but we do not find the recommended changes to be persuasive. While the minimum enrollment threshold for low enrollment PDPs is higher at 1,000 beneficiaries, we do not believe PDPs are an apt comparison. We believe a better comparison for D-SNP look-alikes is the minimum enrollment threshold for low enrollment SNPs, which is 100 enrollees for plans in existence for three or more years, as outlined in the 2020 Final Call Letter.¹⁶ We proposed a minimum enrollment standard of 200 to allow some additional flexibility for initial enrollment patterns that may not be representative of the longer term enrollment pattern for the plan. Once the initial enrollment period has passed or the number of enrollees during that first year of operation exceeds 200 enrollees, we believe the enrollment profile accurately reflects whether or not the plan was designed to exclusively enroll dually eligible individuals. Therefore, we are finalizing the D-SNP look-alike exemption criteria in this final rule at paragraph (d)(2)(ii) to exempt those D-SNP look-alikes active for less than one year and with enrollment less than or equal to 200 enrollees at the time of CMS' determination using January enrollment of the current year.

¹⁶ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf>

Comment: A commenter noted that certain C-SNPs, including ESRD C-SNPs, may enroll a large number of dually eligible individuals and appreciated that we were clear in the proposed preamble that the proposed enrollment threshold for D-SNP look-alikes only applies to non-SNP MA plans.

Response: We welcome the comment's perspective. As we stated in the proposed rule preamble, we proposed applying this requirement only to non-SNP plans to allow for the predominant dually eligible enrollment that characterizes D-SNPs, I-SNPs, and some C-SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. We are finalizing as proposed at paragraph (d) that the prohibition on D-SNP look-alike contracting does not apply to any specialized MA plan for special needs individuals as defined in § 422.2.

Comment: A commenter supported our proposed implementation timing at paragraphs (d)(1) and (2) to allow D-SNP look-alikes operating in 2020 to transition enrollees to other MA plans offered by the D-SNP look-alikes' parent organizations for an effective date of January 1, 2021, and to no longer enter into or renew contracts with D-SNP look-alikes for plan year 2022 and subsequent years. A few commenters suggested that CMS finalize any policy on D-SNP look-alikes in time for plan year 2021 bid preparation, preferably by April 2020, and to ensure a smooth transition for enrollees. Some commenters requested that CMS delay implementation of the proposed changes by requesting a one-year delay, a two-year delay, or by specifically requesting that D-SNP look-alikes be permitted to operate until 2023 or later. A commenter recommended CMS employ an incremental phased-in approach so that plans above the 80 percent enrollment threshold are permitted to continue operating for a longer period of time. Another commenter suggested that, if CMS will not allow at least an additional year for

implementation, CMS allow for continuation of certain plans for the 2022 plan year where the MA organization can demonstrate a good faith effort to apply for and implement a compliant D-SNP product. Commenters cited various reasons for delaying implementation, including allowing MA organizations additional time to file applications, gain approval of compliant D-SNP products, facilitate a smooth transition of enrollees, and consider continuity of care, nuances of state requirements, and market dynamics that might conflict with the proposed rule.

A commenter noted that the need for a delay is particularly important in states where plans' ability to create D-SNPs is limited, and several commenters emphasized the need for sufficient time to develop new products, especially to meet state requirements for integrated plans. A few commenters indicated that CMS' proposed timeline did not align with the California Advancing and Innovating Medi-Cal (CalAIM) initiative to integrate Medicare and Medicaid through D-SNPs and Medicaid MLTSS plans. These commenters expressed concern that, under the proposed timeline, D-SNP look-alike enrollees in California could face multiple Medicare plan transitions in a short period of time, which would potentially disrupt care and confuse beneficiaries. These commenters believed that a later implementation timeframe would allow D-SNP look-alikes extra time to implement a transparent process by which beneficiaries can select plans and transition with minimal disruption.

A commenter noted the additional time necessary for approval of new D-SNPs and a coordinated transition process is especially important given the COVID-19 pandemic. Another commenter requested that CMS allow at least two years for dually eligible individuals, MA plans, states, and other stakeholders to review policy options and devise and implement viable alternatives to CMS' proposal to achieve compliance.

Response: We appreciate the comments supporting the proposed implementation timeline, and we agree with many of the comments recommending that we consider delaying the contract limitation for existing D-SNP look-alikes by one year. While we believe the proposed implementation timeframe remains feasible, we understand that providing an additional year before CMS declines to renew existing D-SNP look-alike plans would give all states and MA organizations more time to consider and collaborate on a more integrated approach and an appropriate transition for enrollees. However, we disagree with the request to delay the proposed dual eligible enrollment thresholds for at least two years. We believe that delaying our implementation of D-SNP non-renewals for one additional year prior will provide sufficient time for MA organizations to develop and seek approval for new plans, coordinate with state integrated care efforts, and facilitate a transparent and smooth transition of beneficiaries.

Therefore, we are finalizing paragraph (d)(2) to provide that CMS will not renew a contract for a D-SNP look-alike starting for plan year 2023 (rather than plan year 2022 as proposed). For plan year 2023, our determination that plans meet the criteria in paragraph (d)(2) would be based on our assessment of the plan's enrollment in January 2022. This will extend by one year the timeline for CMS to non-renew a contract for any non-SNP plan with actual enrollment consisting of 80 percent or more dually eligible enrollees (with the exception of an MA plan active less than one year and with enrollment of 200 or fewer individuals at the time of the determination). Additionally, we are finalizing paragraph (d)(2) with a slight restructuring of using new paragraphs (d)(2)(i) and (ii) for better organization and clarity.

Comments recommending a delay in implementation were based on MA organizations seeking more time to establish new D-SNPs, ensure smooth beneficiary transitions for existing D-SNP look-alike enrollees, and coordinate transitions with state integrated care approaches.

Since these expressed reasons for an implementation delay apply to existing D-SNP look-alikes but not to potential new D-SNP look-alikes that are either in contract application or annual bidding stages, we do not believe there is a need to delay the effective date for the prohibition on CMS not entering into contracts for new D-SNP look-alikes. Implementing the timeline for the prohibition on new D-SNP look-alikes as proposed also avoids the need for additional beneficiary transitions.

We are therefore finalizing our proposal in paragraph (d)(1) that CMS does not enter into a contract – beginning with plan year 2022 – for a new MA plan that projects in its bid submitted under § 422.254 that 80 percent or more of its total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX. We are finalizing paragraph (d)(1) with a slight restructuring of using new paragraphs (d)(1)(i) and (ii) for better organization and clarity. We are retaining the proposed date in paragraph (d)(1), despite changing the date in paragraph (d)(2), to prevent the creation of new D-SNP look-alikes in 2022 that CMS would subsequently non-renew one year later. We are also finalizing as proposed the timeline on which MA organizations will be authorized to transition enrollees from a D-SNP look-alike to another plan, proposed at paragraph (e).

The changes to our proposed policy give MA organizations with existing D-SNP look-alikes more time to coordinate with state integrated care approaches and transition enrollees in a thoughtful, transparent manner that minimizes the number of beneficiary transitions. This finalized approach also allows D-SNP look-alikes that are ready to transition their enrollees the ability to do so as soon as 2021 and eliminates the proliferation of new D-SNP look-alikes, beginning in 2022. We are available to provide guidance to any MA organization regarding transition to a new or existing D-SNP and encourage MA organizations to monitor their Monthly

Membership Reports to determine if they are approaching or above the allowable threshold for dually eligible enrollees in a non-SNP plan in any state where the contracting limitations under this regulation will apply.

Comment: A commenter noted that if an MA organization has not submitted an application for a D-SNP for contract year 2021, it would not be able to transition D-SNP look-alike enrollees in 2021, as the commenter believed was required under CMS' proposal. This commenter added that some states have not yet clarified which plans will be allowed to offer D-SNPs in specific markets for 2021.

Response: We agree with the commenter that the D-SNPs that will operate in specific markets in plan year 2021 are not yet known and will not be public information until fall 2020. However, we believe this commenter may have misunderstood the timing of our proposal. We proposed to allow, but not require, D-SNP look-alikes operating in 2020 to transition enrollees for an effective date of January 1, 2021, and we proposed that CMS not enter into or renew contracts with D-SNP look-alikes beginning January 1, 2022. As explained earlier in this section, we are finalizing paragraph (d)(2) to allow an additional year – until plan year 2023 – before CMS will decline to renew a contract for an existing MA plan that meets our dual eligible enrollment threshold. Under our original proposal, existing D-SNP look-alikes could, but were not required to, transition their enrollees for a January 1, 2021, or a January 1, 2022 effective date before the contract limitation in paragraph (d)(2) requires action by CMS. With our revisions for the final rule, we are also permitting an option for existing D-SNP look-alikes to transition enrollees for a January 1, 2023 effective date. Under the final provisions of § 422.514(d), CMS will permit any new D-SNP look-alike that begins to operate on January 1, 2021 to continue operating until December 31, 2022. However, an MA organization offering

such a new D-SNP look-alike could choose to transition its enrollees as early as January 1, 2022. Further, the transition is not required to be only to a D-SNP, so the MA organization operating an existing D-SNP look-alike does not need to apply to offer a D-SNP.

Comment: A number of commenters preferred an alternative discussed in the proposed rule that would require an MA organization to transition any dually eligible individuals enrolled in a non-renewing D-SNP look-alike into a D-SNP for which they were eligible if such a plan is offered by the MA organization. Some of these commenters believed D-SNP look-alikes should not be able to transition dually eligible individuals into other MA plans when a more integrated option exists. A commenter supported this alternative since it viewed a requirement to transition dually eligible individuals into D-SNPs as continuing federal efforts to strengthen integration of care for dually eligible individuals. A commenter specifically suggested that CMS prioritize transition of full-benefit dually eligible individuals to D-SNP products and other integrated plans.

Response: We appreciate the commenters' support for the proposed alternative, and we share the commenters' preference for integrated care. Although we considered an alternative in the proposed rule that would require transitioning any dually eligible individuals into a D-SNP for which they were eligible if such a plan is offered by the MA organization, we opted for proposing a less prescriptive set of transition rules, recognizing a potentially wide array of transition scenarios. We believe that transitioning D-SNP look-alike enrollees to D-SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, when one is offered by the same MA organization or another MA organization that shares the same parent organization as the MA organization, furthers federal goals to integrate care for dually eligible individuals. However, we also expect that some MA organizations may be unable to transition all

D-SNP look-alike enrollees into the same MA plan, since the D-SNP look-alike enrollees may not all meet the eligibility criteria for a particular special needs plan offered by the MA organization or another MA organization that shares the same parent organization as the MA organization.

Our proposal included language at paragraph (e)(1) to allow MA organizations to transition D-SNP look-alike enrollees into one or more MA plans that meet the criteria proposed at paragraphs (e)(1)(i) – (iii). While we expect and encourage dually eligible enrollee transitions to D-SNPs or other integrated plans to occur in many cases, even in the absence of a specific federal requirement, we believe that the complexities associated with a regulation that prioritizes or restricts transitions to D-SNPs or other integrated plans that way would outweigh the potential benefits. Thus, we are finalizing paragraph (e) that an MA organization with a non-SNP MA plan determined to meet the enrollment threshold finalized at paragraph (d)(2)(ii) may transition enrollees into another MA-PD plan (or plans), including a D-SNP, if offered by the same MA organization, as long as any such MA-PD plan meets certain proposed criteria finalized at paragraph (e) and, if such transition is to a D-SNP, enrollees meet the D-SNP eligibility criteria.

Paragraph (e) allows MA organizations multiple options. First, an MA organization can choose not to participate in any transition process under paragraph (e), in which case the enrollees in a D-SNP look-alike would be enrolled by default in the original Medicare fee-for-service program, unless the enrollee made an active choice otherwise. Second, an MA organization can choose to transition all enrollees from a D-SNP look-alike to a different plan that meets the criteria in paragraph (e)(1). Third, recognizing that D-SNP look-alike enrollees may not all qualify for the same new plan, paragraph (e) allows an MA organization to transition look-alike enrollees to multiple plans. For example, an MA organization could transition from its

D-SNP look-alike: (1) dually eligible enrollees into a D-SNP for which they were eligible and (2) non-dually eligible enrollees into a non-SNP plan, provided both plans meet the criteria in paragraph (e)(1).

MA organizations must abide by the anti-discrimination provision (based on health status) in section 1852 of the Act and § 422.110 and other applicable law (for example, civil rights law) when exercising the transition authority. These provisions are applicable to the enrollment transitions authorized under § 422.514(e) and would be especially important to consider where an MA organization chooses to transition enrollees into more than one MA plan. With the exception of transitioning an individual into a C-SNP, an MA organization must not choose a particular plan for an enrollee to transition into based on health status, if the enrollee were eligible for more than one plan offered by the MA organization or its parent organization to receive transitioned enrollees. For example, it would be a violation of the anti-discrimination provision if an MA organization transitioned most dually eligible members from a D-SNP look-alike to a D-SNP but transitioned dually eligible members with diabetes to a different qualifying non-SNP MA plan. As necessary, we will monitor use of the transition authority under this rule to ensure compliance with the applicable anti-discrimination provisions and may take other action as warranted to protect beneficiaries.

Finally, we note that we intend to inform state Medicaid agencies of transitions of enrollees from D-SNP look-alikes into D-SNPs in their state so the states are aware for purposes of their own integrated care efforts and communications with stakeholders.

Comment: A commenter requested that CMS add language that specifically includes MMPs as a plan type eligible to receive beneficiaries who transition from D-SNP look-alikes. Another commenter requested that states be given the flexibility to transition dually eligible

look-alike enrollees into a D-SNP or other plan authorized by CMS to exclusively enroll dually eligible individuals, such as an MMP.

Response: We appreciate these comments. The proposed language did not explicitly name MMPs as a type of MA plan into which D-SNP look-alike enrollees could transition because MMPs are not defined in regulation, and CMS can facilitate enrollments from D-SNP look-alikes into MMPs under separate authority. We clarify that MMPs are a type of plan authorized to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX. CMS is testing the Financial Alignment Initiative under section 1115A of the Act. Some of the demonstration states in the Financial Alignment Initiative are transitioning individuals from an MA plan, including a D-SNP look-alike, to an MMP through passive enrollment. If an MA organization also sponsors an MMP and desires to transition D-SNP look-alike enrollees to the MMP, we would partner with the state Medicaid agency and use our existing authority and processes to execute the transition. Outside of the context of a demonstration or model test under section 1115A of the Act, however, we do not agree with the commenter's request that states be given the flexibility to transition D-SNP look-alike enrollees. CMS will work directly with D-SNP look-alikes to operationalize the transitions, consistent with other Medicare plan transitions, and ensure states are aware of them.

Comment: A commenter requested that CMS ensure dually eligible individuals who previously received care through a managed care plan do not default into the original Medicare fee-for-service program. The commenter stated that these individuals should have the opportunity and support necessary to choose a plan that meets their needs and does not disrupt their care.

Response: We appreciate the commenter's request and agree with the concern. However, we expect the number of D-SNP look-alike enrollees who enroll in the original Medicare fee-for-service program as a result of this rulemaking to be very small. In our proposed Collection of Information (COI) burden estimates, we estimated that only one percent, or 1,808, D-SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned by the MA organization. Our estimate was based on our experience with the rate of dually eligible enrollees opting-out of passive enrollment from an MA plan to an MMP offered by the same parent organization as part of the Medicare-Medicaid Financial Alignment Initiative.

Comment: A commenter requested that CMS clarify whether the proposed transition approach allows transition of D-SNP look-alike enrollees to MA plans of a different plan type, such as from an HMO to a PPO.

Response: We appreciate the commenter's request for clarification. In the proposed rule, we stated that our proposed transition process was conceptually similar to "crosswalk exception" procedures historically allowed by CMS and proposed at § 422.530 in the proposed rule. We also clarified that, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities offered by MA organizations under the same parent organization, as well as between SNPs and non-SNP plans. However, it was not our intent to allow for the transition process to apply across product types – for example, HMO to PPO, and vice versa. We are therefore modifying the regulation text to add a new paragraph (e)(1)(iv) to stipulate that an MA plan or plans receiving enrollees under the transition process we are finalizing in paragraph (e) must be of the same plan type (for example, HMO or PPO) as the D-SNP look-alike. An MA organization will not be permitted to transition an individual from a D-SNP look-alike PPO to an MA-PD plan that is an HMO, or vice versa.

Comment: A commenter appreciated that our proposed transition gives D-SNP look-alikes the ability to transition non-D-SNP members into a D-SNP across legal entities. This commenter requested that CMS allow transitions across legal entities in other situations where it would be in the beneficiary's best interest, such as transitioning a beneficiary with a chronic condition into a C-SNP under a different legal entity.

Response: The commenter's understanding of our proposed transition approach in § 422.514 in connection with transitioning enrollees out of a D-SNP look-alike is accurate. Our approach, which we are finalizing as proposed at paragraph (e), allows MA organizations to transition D-SNP look-alike enrollees into an MA plan or plans which meet the criteria in paragraph (e)(1) and are offered by the same MA organization or another MA organization that shares the same parent organization as the MA organization. Under our approach, D-SNP look-alike enrollees who are eligible for a C-SNP could be transitioned into a C-SNP that meets the criteria in paragraph (e)(1). With regard to crosswalks or enrollment changes in other contexts, the recommendation is outside of the scope of our proposal for § 422.514; we will take the comment under consideration in connection with the crosswalk proposal (proposed to be codified at § 422.530) in section VI.C. of the proposed rule, which we intend to address in a future final rule.

Comment: Some commenters encouraged CMS to finalize the proposed policy on D-SNP look-alikes with sufficient advance timing, preferably in advance of the 2021 bid deadline, to allow for enrollee transitions.

Response: We agree it is important, where possible, to finalize the policy in advance of bid deadlines so that MA organizations can have sufficient time to make decisions for 2021 plan offerings. At paragraph (d), we are finalizing the timing of when we would implement the

prohibition on contracting for D-SNP look-alikes with the modifications discussed earlier. D-SNP look-alikes operating in 2020 may choose to transition their enrollees effective January 1, 2021, January 1, 2022, or January 1, 2023, and D-SNP look-alikes operating in 2021 may choose to transition their enrollees effective January 1, 2022 or January 1, 2023. For plan year 2022 and subsequent years, CMS will not enter into a contract with a new MA plan that meets criteria outlined in paragraph (d)(1), and for plan year 2023 and subsequent years, CMS will not renew a contract with a MA plan that meets criteria outlined in paragraph (d)(2). We note that MA organizations will be able, under § 422.514(e) as finalized here, to transition enrollees in D-SNP look-alikes to other plans in advance of CMS non-renewing the D-SNP look-alike PBPs effective January 1, 2023 and January 1 of subsequent plan years.

Comment: A commenter noted that D-SNPs currently must have executed state Medicaid agency contracts with applicable states and requested that CMS also allow plans to meet this requirement with subcontracts through a directly contracted entity in order to ease transitions for beneficiaries into the most integrated plan possible.

Response: Consistent with the revised SMAC requirements and the new definition of a D-SNP codified in the April 2019 final rule, a plan must have a direct contract with the state Medicaid agency to meet the definition of a D-SNP at § 422.2. CMS does not consider subcontracting arrangements with Medicaid managed care plans in lieu of SMACs to approve a plan as a D-SNP.

Comment: A commenter recommended that CMS allow an opt-out process for D-SNP look-alike enrollees being transitioned to a new plan. The commenter indicated that such an opt-out process would preserve beneficiary choice.

Response: We appreciate the comment and agree that the ability of an enrollee to opt out is important to ensure beneficiary choice. As we discussed in the preamble of the proposed rule, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA-PD plan (or plans) offered by the same MA organization, as long as any such MA-PD plan meets certain criteria described in the proposed rule and finalized here. Under the transition authority we are finalizing, an MA enrollee could be transitioned from one MA plan offered by an MA organization to another MA-PD plan (or plans) without the enrollee having completed an election form or otherwise indicate their enrollment choice as typically required. However, the timing of these transitions permits the enrollee to make an affirmative choice for another MA plan of his or her choosing during the annual election period (AEP) from October 15 through December 7. Section 422.514(e) ensures this right because the description of the MA plan to which the enrollee would be transitioned must be provided in the ANOC that must be sent consistent with requirements in § 422.111(a), (d), and (e). The ANOC must be sent at least 15 days before the beginning of the AEP. Enrollees would still have the opportunity to choose their own plan during this transition process because of how the proposed transition process would overlap with the annual coordinated election period. If a transitioned enrollee elects to enroll in a different plan during the AEP, enrollment in the plan the enrollee selected would take precedence over the plan into which the MA organization transitioned the enrollee. Transitioned enrollees would also have additional opportunities to select another plan through the Medicare Advantage Open Enrollment Period described in § 422.62(a)(3) from January 1 through March 31. Affected individuals may also qualify for a Special Election Period (SEP), such as the SEP for plan non-renewals at § 422.62(b) or the SEP for dually eligible individuals or Part D low-income subsidy eligible beneficiaries at §

423.38(c)(4). For D-SNP look-alike enrollees who are not transitioned by an MA organization per proposed paragraph (e)(1), the MA organization must send a written notice consistent with § 422.506(a)(2). This requirement will ensure that the content of that notice includes the content sent when a plan is non-renewing (including information about other enrollment options) and that the notice is sent by October 2 (90 days before the end of the year). We believe that the transition process we proposed and are finalizing provides sufficient opportunity for affected enrollees to opt out of their new plan and make a different election. Therefore, as described earlier in this section, we are finalizing the transition process at paragraph (e) largely as proposed with some minor modifications and technical changes described elsewhere in this section.

Comment: A few commenters expressed concern about the disruption of aligned Medicare and Medicaid coverage at the point of transition, especially when an individual is enrolled in a Medicaid plan under the same parent organization as the D-SNP look-alike. These commenters recommended that affected beneficiaries be permitted to stay with the MA plan or MA organization to ensure continued integration of Medicare and Medicaid benefits. The commenters believed that such a disruption in ongoing care plans and care teams at the individual level would likely outweigh any additional benefit from the D-SNP integration requirements at the plan level.

Response: We appreciate the commenters' concerns about potential disruption of aligned coverage. The transition approach proposed and finalized at paragraph (e) permits MA organizations to transition D-SNP look-alike enrollees into another MA plan or plans (including into a D-SNP for enrollees who are eligible for such a plan) offered by that MA organization or by another MA organization that shares the same parent organization. We expect the vast majority of D-SNP look-alike enrollees to be transitioned into a plan offered by the same parent

organization as the D-SNP look-alike, which would facilitate the sharing of any enrollee care plans and, in some cases, continued access to the same care teams. Also, as explained earlier in this section, we estimate that only one percent of D-SNP look-alike enrollees will move to the original Medicare fee-for-service program or to another MA plan outside of the same parent organization. To the extent that any enrollees in a D-SNP look-alike are enrolled in a Medicaid managed care plan under the same parent organization as the D-SNP look-alike, the transition authority finalized in paragraph (e) allows similar enrollment in plans offered by the same entity or parent organization.

Comment: Some commenters requested that CMS consider state-specific integrated care initiatives as it finalizes its transition policy. In particular, a few commenters encouraged CMS to coordinate transition of D-SNP look-alikes with states where integrated care plan initiatives are proposed or underway to avoid unintended confusion or enrollment barriers for dually eligible individuals. A commenter suggested that CMS issue guidance to states about enrollee transitions initiated by D-SNP look-alikes so that transitions of dually eligible individuals are coordinated with any changes that states are proposing in Medicaid enrollment, which would help minimize the number of transitions an individual experiences over a short period of time. A few commenters requested that CMS consider the impacts of any state-imposed moratorium on contracting with D-SNPs in counties where MMPs are offered, citing such a policy in California. A commenter stated that any such moratorium could affect the ability of individuals who have opted out of MMPs or do not meet MMP eligibility criteria to enroll in other integrated plan options. Another commenter noted that D-SNPs are best positioned to meet the unique needs of dually eligible individuals, and the California restrictions on D-SNP enrollment are harmful when dually eligible individuals do not have the flexibility to enroll in a D-SNP. This commenter

expressed concern that if CMS moved forward with the proposed policy and D-SNPs remained closed to enrollment, beneficiaries in areas like those in certain California counties would likely enroll in non-SNP MA plans that not only would not offer the care coordination required by D-SNPs, but may impose higher premiums and out-of-pocket expenses.

Response: We thank the commenters for sharing these concerns. As we stated in our proposed rule preamble, section 164(c)(4) of MIPPA does not obligate states to contract with D-SNPs, which therefore provides states with significant control over the availability of D-SNPs. As discussed earlier, we are finalizing language to delay CMS non-renewal of D-SNP look-alikes to January 1, 2023 and subsequent years, to allow more time for MA organizations and states to coordinate transitions. This delay will also better align the timing of any enrollee transitions from D-SNP look-alikes in California with the current CalAIM implementation timing of January 1, 2023. We do not expect D-SNP look-alike enrollees to experience higher premiums since the transition approach proposed and finalized at paragraph (e) only permits MA organizations to transition D-SNP look-alike enrollees into MA plans that meet certain criteria, including having a combined Part C and Part D premium of \$0 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a).

Comment: A commenter appreciated CMS giving MA plans the ability to transition enrollees in non-D-SNP look-alikes into D-SNPs across legal entities but expressed concern that there could be disproportionate and unintended impacts to the Members Choosing to Leave the Plan Star Rating measure for contracts with the D-SNP look-alikes where the transition authority is used. This commenter requested that CMS ensure that all proposed D-SNP look-alike transitions are excluded from the Members Choosing to Leave the Plan Star Rating measure because the commenter did not believe this measure, which is representative of enrollee

satisfaction, would accurately reflect performance if transitioned members were included in the measure.

Response: We thank the commenter for raising this issue. The specifications for the Members Choosing to Leave the Plan Star Rating measure allow beneficiaries transitioned as a result of a PBP termination to be excluded from the calculation of this Star Rating measure. The vast majority of D-SNP look-alike enrollees transitioned into another MA plan or plans will be identified in MARx as disenrollment reason code 09, termination of a contract (CMS-initiated), or disenrollment reason code 72, disenrollment due to a plan-submitted rollover. Neither disenrollment reason code 72 nor 09 will be counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. As discussed earlier, we estimated one percent of, or 1,808, D-SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned. MARx will identify these transitions as disenrollment code 13, disenrollment because of enrollment in another plan, and these transactions will be counted toward calculation of the Members Choosing to Leave the Plan Star Rating measure. Since such a small number of transitioning D-SNP look-alike enrollees would be counted, we do not believe a change to the Star Rating measure specifications is needed.

Comment: Some commenters requested that CMS only permit D-SNP look-alikes to transition members into other MA plans for which provider networks have at least a 90 percent overlap with the provider network of the D-SNP look-alike. These commenters requested that, if this standard is not met, enrollees should not be transitioned to another plan and instead default to coverage under the original Medicare fee-for-service program. One of these commenters noted that because any plan receiving D-SNP look-alike enrollees would be part of the same parent

organization as the D-SNP look-alike, that parent organization could adjust the MA plan networks to meet this 90 percent standard.

Response: We appreciate the commenters' concern that dually eligible individuals maintain their providers from the network of the D-SNP look-alike. As we discussed in response to other comments, MA organizations may transition enrollees from a D-SNP look-alike into another MA plan offered by the same parent organization, including a D-SNP. Many provider participation agreements used by MA organizations include provisions that the providers contract for all product types the MA organization offers. In fact, CMS assesses network adequacy at the contract level rather than at the plan level (see section V.A. of this preamble). In similar instances where CMS transitioned enrollees from MMPs to D-SNPs under the same parent organization, there was a high degree of overlap in the provider network, as assessed at the contract level. Based on our understanding of common contracting processes and past experience with MMPs and MA organizations that offer D-SNPs, we believe a high degree of overlap will exist between the contracted provider networks in a D-SNP look-alike and a MA plan offered by the same parent organization, making it unnecessary for CMS to impose a standard that requires a specific percentage of provider overlap. Additionally, and as we noted earlier in this section, in those instances where a dually eligible individual receives notice that they are being transitioned to a MA plan that does not include their providers, they retain the ability to choose a different MA plan or the original Medicare fee-for-service program. Finally, in any instances in which there would be meaningful network differences between the D-SNP look-alike and the MA plan to which a member is transitioned, we strongly encourage plans to communicate with members about the potential impacts of such changes.

Comment: A commenter explained that there were many lessons learned during the implementation of Cal MediConnect, a capitated model demonstration under the Financial Alignment Initiative, that highlighted the importance of consumer protections such as continuity of care and network parity. The commenter noted that during the transition to Cal MediConnect, the Department of Health Care Services, California's state Medicaid agency, implemented continuity of care standards and provided guidance allowing the receiving Cal MediConnect plan, which was an MMP, to use the HRA completed by a D-SNP. To minimize disruptions in care, the commenter requested that CMS consider beneficiary protections similar to those included in the state's proposed CalAIM D-SNP transition plan and establish requirements for transferring a D-SNP look-alike enrollee's HRA and care plan, as well as requirements for continuity of care and network parity, and a prohibition on receiving plans' imposition of additional cost-sharing requirements.

Response: We appreciate the commenter's perspective and support a smooth transition between D-SNP look-alikes and another MA plan, but we do not believe establishing additional requirements as suggested is necessary. As discussed in the preamble of our proposed rule, D-SNP look-alikes are not subject to federal D-SNP requirements, including the requirements to develop HRAs and individualized care plans. Thus, we do not expect D-SNP look-alikes necessarily will have any HRAs or care plans to transfer to another MA plan in connection with the transition of a beneficiary's enrollment. As discussed earlier in this section, to the extent that a D-SNP look-alike has developed HRAs or individualized care plans, we expect the vast majority of D-SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D-SNP look-alike. We believe that transitions under paragraph (e) will facilitate the sharing of any HRAs and care plans and promote continuity of care because the

new plan will be operated by an entity with the same parent organization, if not the same MA organization, which likely means overlapping or the same personnel and policies. Additionally, all transitioning beneficiaries will have Medicare's standard Part D continuity of care protections for prescription drugs (including temporary fills of non-formulary drugs during a transition period as provided under § 423.120(b)(3)). Plans receiving transitioned enrollees must also provide other continuity of care requirements for MA plans, including those outlined in § 422.112(b). As we describe earlier in this section, we believe that there will be a high degree of provider network overlap across plans that are offered by the same MA organization or share a parent organization, making it unnecessary for CMS to impose a standard that requires a specific percentage of provider overlap. Finally, we do not expect D-SNP look-alike enrollees to experience higher premiums since the transition approach proposed and finalized at paragraph (e) only permits MA organizations to transition enrollees in a D-SNP look-alike into MA plans that meet certain criteria, including having a combined Part C and Part D premium of \$0 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a). We also note that, pursuant to § 422.504(g)(1), MA organizations cannot impose cost sharing requirements for Medicare Parts A and B services on full-benefit dually eligible individuals that would exceed the amounts permitted under the state Medicaid plan if the individual were not enrolled in the MA plan.

Comment: Several commenters encouraged CMS to require that the ANOC notifying a beneficiary being transitioned to a new plan identify D-SNP look-alike providers known to not be in the receiving plan's network, focusing specifically on primary care providers and specialists who the beneficiary has seen twice or more in the past year. One of these commenters explained that this information would help beneficiaries make informed choice about whether to

participate in the transition and prevent surprise access-to-care issues in the early months of enrollment. A commenter expressed a similar view but suggested the ANOC identify any providers seen in last year. Another commenter noted the importance of a plan's provider network to beneficiaries with disabilities. We also received one comment recommending that the ANOC contain information about other plan options.

Response: We appreciate the commenters' perspectives and support transparency on MA provider networks, but we do not agree that the ANOC is an appropriate means of communicating beneficiary-specific provider information since it is not a beneficiary-specific notice. Standardized language in the ANOC model already provides general information about changes to an MA plan's network and directs enrollees to the plan's updated provider network directory to help with decision-making during the AEP. As we discussed earlier in this section, we believe the vast majority of D-SNP look-alike enrollees will be transitioned into an MA plan within the same parent organization as the D-SNP look-alike and there will be a high degree of provider network overlap across plans that are offered by the same MA organization or share a parent organization, lessening the need to provide beneficiary-specific provider information. Additionally, and as we noted earlier in this section, in those instances where a dually eligible individual is transitioned to a MA plan that does not include their providers, they retain the ability to choose a different MA plan or the original Medicare fee-for-service program.

While we support beneficiary education and choice about plan options, we also do not believe the ANOC is the appropriate vehicle for communicating information about other plan options. As described earlier, the transition process of D-SNP look-alike enrollees into another MA plan or plans will overlap with the AEP. Enrollees who are subject to being transitioned under § 422.514(d) have multiple ways of identifying other plan choices, such as through

reviewing the Medicare & You Handbook, consulting Medicare Plan Finder, and contacting 1-800-Medicare and the State Health Insurance Assistance Program in their state.

Comment: A commenter requested that CMS provide guidance for providers and beneficiaries explaining why the transition from D-SNP look-alikes to another MA plan or plans is occurring.

Response: We appreciate the comment and the desire for providers and beneficiaries to be informed about the transition. However, we believe it is the responsibility of MA organizations that are transitioning enrollees to other MA plans to educate providers and enrollees about the transition and the benefits of the new (receiving) plans. As discussed earlier in this section, the MA organization receiving D-SNP look-alike enrollees is required to send these enrollees an ANOC consistent with § 422.111(a), (d), and (e) that includes information on benefits and provider network changes. We are, however, finalizing paragraph (e)(2)(ii) with minor modifications to clarify that the responsibility of providing information to transitioned enrollees in the ANOC rests with the MA-PD plan into which individuals are transitioned, and that the ANOC describes changes to the MA-PD plan's benefits and provides information about the MA-PD plan.

Comment: A commenter expressed support for the proposed D-SNP look-alike contracting standards, while noting potential negative impacts, including reduced plan competition and consumer choice. The commenter recommended that states be required to contract with all MA-PD plans that have an approved MOC and suggested three different contracting options: 1) states enter into a care coordination contract with plans; 2) states pay plans to coordinate Medicare and Medicaid services, assuring alignment with the state's strategy to deliver LTSS or managed LTSS (MLTSS); and 3) states pay plans to coordinate Medicare and

Medicaid services and deliver LTSS. Another commenter suggested that plans meeting certain CMS criteria for integrated care could earn a “Standard of Excellence for Dually-Eligible Individuals” seal of approval that could be used for marketing purposes and posting on Medicare Plan Finder.

Response: We appreciate the commenters’ input on strategies that could improve plan competition and support consumer choice. We note that some of the commenters’ recommendations, such as requiring states to contract with all MA-PD plans that have an approved MOC, are beyond CMS’s existing authority. As we gain experience with implementing the requirements in this final rule, we will take into consideration those recommendations that are within CMS’s authority.

Comment: A commenter recommended CMS consider requiring that any entity that meets the 80 percent dual enrollment threshold meet minimum standards of integrated care coordination and data sharing for its full-benefit dually eligible members, including in the eight states that do not currently have any D-SNPs (as of July 2019). This commenter supported requiring that MA organizations in these eight states transition members to an MMP if one exists or, if one does not, submit a MOC, complete HRAs, and provide integrated care coordination and information sharing for all of its full-benefit dually eligible members.

Response: We appreciate the commenter’s alternative approach. We clarify that proposed paragraphs (d)(1) and (2) would, in fact, limit new and existing D-SNP look-alikes from operating in states where a D-SNP or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX, including MMPs, exists. The limit on new D-SNP look-alikes precludes CMS from entering into a new contract for a D-SNP look-alike for 2022 and subsequent years. The limit on existing D-SNP look-alikes

precludes CMS from renewing a contract for an existing D-SNP look-alike for 2023 and subsequent years. However, under current law, CMS does not have the authority to require D-SNP look-alikes in the eight states without D-SNPs to submit MOCs, conduct HRAs, or provide integrated care coordination and information for all of its full-benefit dually eligible members. Section 1859(f) of the Act requires that each D-SNP have a contract with the state Medicaid agency; this requirement is in addition to other D-SNP requirements this commenter references. Allowing D-SNP look-alikes to operate without such state contracts would allow such plans to circumvent an important D-SNP requirement.

Comment: A few commenters proposed the application of new federal measures nationwide that would require D-SNP look-alikes to make progress on a pathway toward greater care integration. Rather than not approving or renewing contracts for certain D-SNP look-alikes, a commenter suggested that this alternative approach would assure continued beneficiary choice, as certain integrated care plans receive lower Star Ratings than other plans that do not provide integrated care. Another commenter suggested that D-SNP look-alikes could provide more integrated care if CMS required them to notify the state Medicaid agency or appropriate Medicaid managed care plan when full-benefit dually eligible individuals are admitted to a hospital or skilled nursing facility (that is, the requirement recently codified at § 422.107(d) as one of three integration options available to D-SNPs beginning in 2021).

Response: We appreciate the support for increased opportunities to integrate care for individuals who are dually eligible and the importance of beneficiary choice. Though we intend, through this final rule, to discourage the rapid proliferation of D-SNP look-alikes that undermine the statutory and regulatory framework for D-SNPs, we will continue to consider other ways to further promote integrated care for individuals who are dually eligible.

Comment: A few commenters proposed that CMS conduct additional research on the market dynamics of D-SNP look-alikes, noting factors such as incentives for brokers who steer enrollees toward or away from certain service delivery models. These commenters suggested that, rather than implementing broad restrictions on D-SNP look-alikes, CMS could address those market distortions directly. For example, if D-SNP look-alikes result from inappropriate steering of beneficiaries, these commenters noted that CMS could institute measures reinforcing referrals to products best suited to the beneficiary's needs. A few commenters noted that if misleading marketing practices were found to be a root cause, CMS has regulations and program rules to stop them. Another commenter supported the strong enforcement of existing marketing and broker requirements to prevent the targeting of dually eligible individuals for marketing MA plans that do not offer integrated care. The commenter noted that if CMS believes it lacks the authority required to discontinue this behavior, Congress should grant the agency the authority it needs.

Response: We appreciate the commenters' perspectives on the need to avoid beneficiary confusion and take steps against misleading marketing practices. Our proposed rule included various proposed provisions codifying previous subregulatory guidance from the Medicare Communications and Marketing Guidelines prohibiting non-D-SNP plans from marketing their plan as if it were a D-SNP; those proposals will be addressed in a future final rule. We note, however, that MA organizations remain responsible for ensuring that their agents and brokers comply with part 422, subpart V. Current requirements (such as § 422.2268(a)(1) and (2)) include prohibitions on misleading or confusing marketing and communications; MA organizations must ensure downstream entities – such as their agents and brokers – that perform marketing or enrollment on behalf of the MA organization also comply with these requirements.

We will also continue to monitor plans' compliance with CMS marketing rules prohibiting misleading marketing practices, including activities of agents and brokers, to ensure that dually eligible individuals can make informed choices. This includes review of complaints about inappropriate marketing practices CMS receives through the Complaint Tracking Module described in § 422.504(a)(15). As we gain experience with implementing the requirements in this final rule, we will evaluate whether additional rulemaking on marketing practices is necessary.

Comment: A few commenters suggested improving and increasing education for dually eligible individuals and providers about the benefits of integrated care and the availability of plans that offer such care. A few commenters suggested that brokers should be required to educate dually eligible individuals on the integrated care options within their service area to assure that they can make informed choices. A commenter recommended that CMS require any low-premium MA plan that attracts dually eligible individuals to educate them about the availability of D-SNP options within their service area.

Response: We appreciate recommendations for improved provider and beneficiary education on the availability and benefits of integrated products, and we will take into consideration ways to strengthen agent and broker training requirements and marketing rules within our current authority.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.514(d) and (e) with the following modifications:

- We are reorganizing the regulation text by adding new paragraphs (d)(1)(i) and (ii) and (d)(2)(i) and (ii) for better organization and clarity of the final requirements, as well as to establish different effective dates for the provisions of paragraphs (d)(1) and (2). Accordingly,

we are also updating the reference in paragraph (e)(1)(i) from paragraph (d)(2) to paragraph (d)(2)(ii).

- We are finalizing the provision at paragraph (d)(2) with the date 2023 instead of 2022 to extend by one year the timeline on which the contract limitation will apply to an existing non-SNP plan with actual enrollment consisting of 80 percent or more dually eligible enrollees (with the exception of an MA plan active less than one year and with enrollment of 200 or fewer individuals at the time of the determination).

- We are modifying paragraph (e)(1)(iv) to stipulate that an MA plan (or plans) receiving enrollees under the transition process in paragraph (e) must be of the same plan type (for example, HMO or PPO) as the D-SNP look-alike.

- We are making a minor modification to paragraph (e)(2)(ii) to eliminate the reference to § 422.2267(e)(3), as that proposed provision is not being finalized in this rule. We are also modifying paragraph (e)(2)(ii) to clarify that the responsibility of providing information to transitioned enrollees in the ANOC rests with the MA-PD plan into which individuals are transitioned, and that the ANOC describes changes to the MA-PD plan's benefits and provides information about the MA-PD plan.

- We are finalizing paragraph (e)(4) with a technical change to clarify that the content as well as the mechanism and timing requirements in § 422.506(a)(2) apply to the notice an MA organization must provide to any enrollees in a D-SNP look-alike that the MA organization is not transitioning to a new plan.

- We are adding a new paragraph (f) to clarify that we would consider actions taken consistent with paragraph (d) to warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion

pursuant to §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

DISCLAIMER: Based on the tight time constraints and the need to expedite the clearance process to ensure timely publication, OSORA will be simultaneously reviewing this document as part of this clearance process. Specifically, we will be ensuring that the regulation is in compliance with the Office of the Federal Register and the Government Printing Office publication guidelines to include: conforming regulation text, assuring the regulation text and preamble are consistent, the responses to the public comments are responsive, and the document justifies our rationale for finalizing a policy.

III. Implementation of Certain Provisions of the 21st Century Cures Act

A. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

Section 4001 of the Balanced Budget Act of 1997 (hereinafter referred to as the BBA of 1997) added sections 1851 through 1859 to the Act establishing Part C of the Medicare program known originally as “Medicare + Choice” and later as “Medicare Advantage (MA).” As enacted, section 1851 of the Act provided that every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end stage renal disease (ESRD), could elect to receive benefits through an MA plan. The statute further permitted that, in the event that an individual developed ESRD while enrolled in an MA plan or in a health plan offered by the MA organization, he or she could remain in that MA plan or could elect to enroll in another health plan offered by that organization. These requirements were codified at § 422.50(a)(2) in the initial implementing regulations for the Part C program published in 1998 (63 FR 35071).

Section 1851 of the Act was subsequently amended several times to expand coverage of ESRD beneficiaries in MA plans.

- Section 620 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (hereinafter referred to as BIPA), established a one-time opportunity for

individuals, medically determined to have ESRD, whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, to enroll in another MA plan.

- Section 231 of the MMA gave the Secretary authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. Under this authority, CMS undertook rulemaking to allow individuals with ESRD to join an MA special needs plan.

In 2016, paragraph (a) of section 17006 of the Cures Act further amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. This change is effective for plan years beginning on or after January 1, 2021. (Please see sections III.B. and III.C. of this final rule for further changes established by section 17006 of the Cures Act.) To implement these changes in eligibility for MA plan enrollment made by the Cures Act, we proposed the following amendments:

- Section 422.50(a)(2) would be revised to specify that the prohibition of beneficiaries with ESRD from enrolling in MA plans (and associated exemptions) is only applicable for coverage prior to January 1, 2021.

- Section 422.52(c) would be revised to specify that CMS authority to waive the enrollment prohibition in § 422.50(a)(2) to permit ESRD beneficiaries to enroll in a special needs plan would also only be applicable for plan years prior to 2021.

- Section 422.110(b) would be revised to specify that the exception to the anti-discrimination requirement, which was adopted to account for the prohibition on MA enrollment by beneficiaries who have ESRD, is only applicable for plan years prior to 2021.

As noted earlier, the changes mandated by the Cures Act do not take effect until the 2021 plan year. As such, individuals entitled to Medicare Part A and enrolled under Part B, and

medically determined to have ESRD, are not eligible to choose to receive their coverage and benefits through an MA plan prior to plan year 2021, subject to the limited exceptions reflected in the current regulation text.

We received a large number of comments related to this proposal. The discussion below pertains specifically to comments related to eligibility and the removal of the prohibition on beneficiaries with ESRD enrolling in an MA plan as proposed in §§ 422.50(a)(2), 422.52(c), and 422.110(b).

Comment: Generally, all commenters supported the statutory change removing the prohibition for ESRD beneficiaries to enroll in an MA plan. Many commenters noted that allowing these beneficiaries to enroll in MA plans will provide care coordination and, thus, improved clinical outcomes for this vulnerable population. A commenter also noted that MA beneficiaries have a relatively low rate of switching among plans and tend to stay with the selected plan long term, and this could contribute to better outcomes through longer coordination of care. Many commenters stated that this change will provide options for obtaining supplemental benefits and access to health and wellness programs not available in Original Medicare.

Several commenters stated that MA plans provide a maximum out-of-pocket (MOOP) cost sharing for all enrollees, which makes MA an attractive option for these beneficiaries with high annual medical costs. Commenters noted that this MOOP may significantly decrease patients' out-of-pocket costs. A commenter noted that the MOOP is especially important for those ESRD beneficiaries who are under age 65, and may not be eligible to purchase a Medigap policy to supplement their Original Medicare expenses. Several commenters noted that this

provision will help improve the lives of, and empower, ESRD beneficiaries consistent with the President's Executive Order on Advancing American Kidney Health.

Response: We agree with the commenters and appreciate their support of the proposal.

Comment: Several commenters requested that CMS clarify if the current optional employer/union group waiver for enrollment of ESRD members will be eliminated and, if so, questioned when guidance would be updated to reflect the change.

Response: Under Section 1857(i) of the Act, CMS has the statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union-sponsored MA plans. As noted in the Medicare Managed Care Manual Chapter 9, section 30.3, CMS used this authority to grant a waiver to allow MA plans offered by MA organizations under contract with an employer or union, or offered directly by an employer or union, to choose to accept enrollees with ESRD under certain circumstances, provided that all otherwise eligible individuals with ESRD are permitted to enroll. With the enactment of the Cures Act, effective plan years on or after January 1, 2021, the prohibition on MA enrollment for ESRD beneficiaries is removed. Therefore, the waiver will no longer be effective and MA plans, including MA EGWPs, must accept enrollments of ESRD beneficiaries. We plan to update guidance as soon as possible.

Comment: A commenter questioned if the 30-month coordination of benefits period for those entitled to Medicare based on ESRD status will be eliminated based on the removal of the prohibition.

Response: The regulation codifies that those individuals with ESRD cannot be restricted from enrolling in an MA plan. However, nothing in the language of the regulation eliminates or is to be construed as eliminating the 30-month coordination of benefits period that section

1862(b)(1) of the Act imposes with regard to Medicare coverage of beneficiaries whose entitlement is based on ESRD. In other words, any Group Health Plan coverage effective at the time a beneficiary with ESRD enrolls in an MA plan will remain the primary payer during the 30-month coordination of benefits period.

Comment: A commenter questioned how removing the prohibition on individuals with ESRD from enrolling in MA plans will impact the way ESRD information must be obtained and reconciled in order to ensure appropriate payment. The commenter also questioned if CMS is considering increasing resources for the QualityNet helpdesk, as ESRD enrollments in MA plans are likely to increase, which may prompt higher volumes of cases where ESRD statuses and payments need to be reconciled and corrected in the future.

Response: Completion of the CMS-2728-U3 form (*End Stage Renal Disease Medical Disease Evidence Report – Medicare Entitlement and/or Patient Registration*, OMB control number 0938-0046) by a dialysis center, (including physician attestation and patient signature) is required for an individual to be medically determined to have ESRD for purposes of filing for Medicare benefits. However, collection of these data on the CMS-2728-U3 are also used to establish and maintain a nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant, regardless of Medicare status. CMS enrollment systems ultimately receive this information resulting in MA plans receiving payment based on ESRD capitation rates and risk adjustment. Further information on this process can be found in section 6.2.2 of the *Plan Communication User Guide for Medicare Advantage Prescription Drug Plans*.

At this time, we have no plans to add additional resources to the QualityNet Help Desk but we will monitor call volumes to see if we need to increase the number of agents fielding ESRD Quality Reporting System calls.

Comment: A commenter requested clarification on whether MA plans will be allowed to include the question regarding ESRD status on the MA enrollment form. The commenter also questioned if this change will impact the required Data Elements to consider an enrollment request complete.

Response: CMS has proposed changes to the standard (“long”) model form used for MA and Prescription Drug Plan (PDP) enrollment (currently approved under OMB control number 0938-0753 CMS-R-267), to reduce data collection and simplify the enrollment process. When adopted, the new, “shortened” enrollment form will limit data collection to what is lawfully required to process the enrollment and other limited information that the sponsor is required, or chooses to, provide to the beneficiary. The new “shortened” form used for enrollment into MA and PDP plans will not contain the ESRD status question. We expect MA plans to use the new shortened form, (once OMB has approved its use) for the 2020 AEP, which begins on October 15, 2020, for January 1, 2021 effective dates. This timeframe aligns with the effective date of the removal of the prohibition of MA enrollment for ESRD beneficiaries. As the ESRD status question will not be on the form, it is not a data element which will be required to consider the enrollment complete. MA plans do not need to know the ESRD status of an enrollee to process an enrollment in light of the changes made by the Cures Act, and are prohibited from discriminating against potential enrollees on the basis of a health status factor. Data element requirements will be updated in future guidance.

Comment: A commenter questioned how CMS plans to work with state Medicaid agencies regarding implementation of ESRD enrollment in D-SNPs. Specifically, the commenter stated that some states do not permit enrollment into a D-SNP plan when a beneficiary has been diagnosed with ESRD and questioned how CMS plans to address the discrepancy between current state enrollment restrictions prohibiting patients with ESRD from enrolling in a state's D-SNP plans and the removal of the prohibition. The commenter also questioned if CMS will require states to adopt policies or align with CMS' enrollment changes.

Response: States already have the ability in their state Medicaid agency contract with each D-SNP to restrict which dually-eligible individuals may enroll in the D-SNP. If the state's contract with a D-SNP excludes those with ESRD, the D-SNP may retain that exclusion in order to comply with the state contract required under § 422.107.

Comment: A commenter questioned how the enrollment change will affect MMPs. They specifically questioned if CMS and state Medicaid agencies will revise the three-way-contracts and if MMP plan rates would be affected.

Response: We note that currently, most states that are testing a capitated model of integrated care in demonstrations under the Financial Alignment Initiative (FAI) authorized under section 1115A of the Act permit those beneficiaries with ESRD to enroll in MMPs. Only South Carolina and six counties in California exclude those with ESRD from enrolling in an MMP. We are consulting with those two states to determine if, starting CY2021, they want to continue that exclusion under the model of integrated care being tested under the FAI demonstration authority. If they decide they do want to include the ESRD population, CMS would work with those states to update the applicable Medicaid MMP rates, as needed. The MMP Medicare rate structure already includes rates specific for individuals with ESRD and

these rates would apply for any MMP enrollees with ESRD; specifically, the ESRD dialysis state rate applies for individuals in the dialysis and transplant status phases, and the Medicare Advantage 3.5 percent bonus county rate applies for individuals in the functioning graft status phase, with all of these rates risk adjusted using the Hierarchical Condition Category -ESRD risk adjustment model for the applicable year.

Comment: A commenter stated that a disproportionate share of beneficiaries with ESRD could be enrolling in D-SNPs and requested that CMS monitor enrollment of beneficiaries with ESRD into D-SNPs and ensure that payments are adequate.

Response: We appreciate the feedback provided by the commenter. We will continue to analyze these issues as additional data emerges. We will consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the ESRD rate setting methodology may be warranted in future years.

Comment: A commenter stated that there should be oversight and penalties for companies who use aggressive marketing campaigns to recruit ESRD patients and “bait and switch” with services the beneficiary was promised and not delivered.

Response: We appreciate the commenters’ concerns. MA plans must comply with the marketing and communications requirements in 42 CFR part 422, subpart V, and specifically, § 422.2268(a)(1) and (2), which include prohibitions on providing information that is inaccurate or misleading, and engaging in activities that could mislead or confuse Medicare beneficiaries. As part of ensuring their compliance with these requirements, MA organizations must monitor and oversee the activities of their subcontractors, downstream entities, and/or delegated entities as well. If CMS finds that MA plans have failed to comply with applicable rules and guidance,

CMS may take compliance or enforcement actions, including, but not limited to, intermediate sanctions or civil money penalties.

Comment: Some commenters raised concerns with implementing new rules given the ongoing COVID-19 pandemic and the strain it is putting on the entire United States health care system. A few commenters urged CMS to consider delaying implementation of this change and continue to prohibit beneficiaries with ESRD from enrolling in MA plans until at least 2022. A commenter requested that CMS consider making all new 2021 requirements voluntary rather than mandatory.

Response: The statutory change provides beneficiaries with the right to make an election for an MA plan if they meet the otherwise applicable requirements beginning January 1, 2021. CMS lacks authority to delay implementation of this statutory change. We are sympathetic to the commenters' concerns that additional changes during the on-going pandemic may increase burdens and make compliance more difficult. However, the pandemic has further indicated that it is important to break down the barrier that has prohibited beneficiaries with ESRD from the enrolling in MA and having access to benefits such as care coordination and limitations to out-of-pocket costs. We also note that these changes are required by law (the Cures Act), effective for plans years on or after 2021. We appreciate that the COVID-19 pandemic has interrupted timing for implementing new requirements, but we are also mindful of the fact that the Cures Act was enacted in 2016 and, as a result, plans have been aware of the change and are likely planning for these enrollments.

Comment: Several commenters suggested that CMS develop educational materials that will provide accurate and objective information about MA plan availability and options, services provided, and potential out-of-pocket costs. A commenter requested that CMS provide clear and

easy to understand rules that prohibit discriminatory behavior so that patients that are entitled to Medicare Part A and enrolled in Part B know how they can exercise their right to select an MA plan.

Response: Thank you for the comments. We agree, and as we implement this new and important policy, we will continue to provide educational and outreach materials and other clear guidance to those beneficiaries that are entitled to Medicare Part A and enrolled in Part B. CMS has reviewed, and will continue to review beneficiary publications to identify potential areas for improvement, and update public facing documents as needed so that Medicare beneficiaries are able make an informed coverage choice.

Comment: A commenter stated that it is important for individuals with ESRD to have access to MA plan options through special election periods (SEPs) for exceptional conditions. A commenter stated that an ESRD beneficiary should understand his or her option to change back to Original Medicare. Another commenter noted that if people sign up for MA and they realize it is not the option for them, they should have the ability to modify their enrollment, switch plans, or to cancel and return to Original Medicare.

Response: We agree that beneficiary choice is important and beneficiaries with ESRD – like all other beneficiaries – should carefully consider their enrollment options when they become eligible for Medicare and during subsequent AEPs. All beneficiaries who join an MA plan have opportunities to change plans or return to the original Medicare fee-for-service program during the AEP (October 15 through December 7) or the Medicare Advantage Open Enrollment Period (January 1 through March 31, and during the first three months of Medicare Part A entitlement and Part B enrollment). In some cases, such as when a beneficiary moves out of the service area or is in a plan that does not renew its contract, a SEP is available. Of

particular note is the “SEP65,” wherein an MA eligible individual who elects an MA plan during his or her initial enrollment period for Part B surrounding his or her 65th birthday may disenroll from this MA plan and elect coverage through the original Medicare fee-for-service program any time during the 12-month period that begins on the effective date of coverage in the MA plan. Beneficiaries may also use SEPs for exceptional conditions newly codified in § 422.62(b)(4) through (25) and described in section 30.4.4 of Chapter 2, Medicare Managed Care Manual, as appropriate, including the SEP for Individuals with ESRD Whose Entitlement Determination Made Retroactively to enroll in an MA plan. Further, to the extent that there is an exceptional situation for an individual that is not addressed by our existing SEPs, codified in this final rule, we will have the ability to respond to the exceptional situation pursuant to § 422.62(b)(26). Finally, there are SEPs available, under § 422.62(b)(3), in situations where the MA plan fails to provide medically necessary services or the plan (or its agents) materially misrepresented the plan’s provisions in marketing materials.

Comment: A commenter suggests the establishment of an ESRD ombudsman to address any issues with implementation of this expansion of MA eligibility that may arise for beneficiaries, MA organizations, or their contracted providers.

Response: The Medicare Beneficiary Ombudsman is dedicated to resolving complaints, grievances and requests for information submitted by Medicare-eligible individuals and their advocates concerning any aspect of the Medicare program. Other entities and resources, including the CMS Regional Offices, State Health Insurance Assistance Programs, and 1-800-MEDICARE are also available to assist beneficiaries with issues or questions.

Comment: A commenter proposed that CMS update the enrollment guidance to remove ESRD enrollment restrictions and to release the updated guidance in April. The commenter

further states that the technology and process updates necessary for plans to implement the changes and the increase in MA membership has led to an increase in the number of materials that plans need to produce, straining production timelines.

Response: Thank you for the comment. We understand the commenter's concern and plan to issue guidance as soon as possible. We are also mindful of the fact that the Cures Act was enacted in 2016 and, as a result, MA organizations have been aware of this change for some time.

Comment: A commenter suggested that dialysis cost sharing be included in the standard services/items reflected on individual plan searches in the Medicare Plan Finder (MPF) tool, and added that this information is not currently reflected.

Response: We appreciate and agree that this additional data will help Medicare beneficiaries with ESRD find and choose an MA plan. We plan to add this information for plans offering coverage in 2021.

Comment: A couple of commenters agreed with our decision not to amend § 422.66(d)(1) (requiring MA organizations to accept newly eligible Medicare beneficiaries who are seamlessly converting from health plan coverage offered by the MA organization) because the provision already applied to all beneficiaries regardless of their ESRD status. A commenter suggested that CMS slightly modify § 422.66(d)(1) to remove the language, "(regardless of whether the individual has end-stage renal disease)" to eliminate any confusion about the prohibition no longer being in effect.

Response: We thank the commenters for their feedback. We believe that the regulation does not require further amendment.

Comment: Commenters also provided a wide range of feedback regarding other downstream issues related to this change in enrollment criteria for the MA program including assurance of adequate payment for plans, quality of care, HEDIS measure changes, beneficiary MOOP and cost-sharing policies, and network adequacy. A commenter suggested that beneficiaries are likely to have improved outcomes if enrolled in a plan that uses an established care delivery model, and several other commenters requested that CMS allow MA plans to participate in the Center for Medicare & Medicaid Innovation kidney models to improve the dissemination of best practices in kidney care. Another commenter requested that CMS develop and submit SSBCI benefits for these beneficiaries.

Response: We appreciate commenters for their feedback. Since those comments are outside the scope of the changes proposed in §§ 422.50(a)(2), 422.52(c), and 422.110(b), they will not be addressed in this section. To the extent that the comment is about other proposals in the notice of proposed rulemaking, it is, or will be, addressed in connection with that proposal elsewhere in this final rule or a future final rule.

After review and consideration of all comments on the proposal to remove the prohibition on ESRD beneficiaries enrolling in an MA plan and for the reasons in the proposed rule and these comments and responses, we are finalizing the revisions to §§ 422.50(a)(2), 422.52(c), and 422.110(b) as proposed.

B. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

The MA organization is generally responsible for furnishing or providing coverage of all Medicare Part A and Part B benefits, excluding hospice, for its enrollees. The Medicare FFS program does not pay health care providers for furnishing these benefits to such enrollees.

Section 1851(i) of the Act generally provides that, subject to specific exceptions, CMS pays only the MA organization for the provision of Medicare-covered benefits to a Medicare beneficiary who has elected to enroll in an MA plan. There are specific, statutory exceptions to this general rule in the statute, such as authority in section 1853(h) of the Act for FFS Medicare payment for Medicare-covered hospice services that an MA plan is prohibited by statute from covering.

Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the list of items or services an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program, pursuant to an amendment by section 17006(c)(2) of the Cures Act to section 1851(i) of the Act. As amended, section 1851(i)(3) of the Act authorizes FFS Medicare payment for the expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We proposed conforming regulatory changes to reflect the revision to the statute.

Specifically, we proposed to revise § 422.322, which describes the source of payment and effect of MA plan election on payment for Medicare-covered benefits. Paragraphs (b) and (c) of § 422.322 generally track the statutory requirements that, subject to specific exceptions, CMS payment to MA organizations is in lieu of the amounts that would otherwise be payable under the original Medicare FFS program for Medicare-covered benefits furnished to an MA enrollee and are the only payment by the government for those Medicare-covered services. Consistent with the amendments to sections 1851(i) and 1852(a)(1)(B)(i) of the Act, we proposed to amend § 422.322 to add a new paragraph (d) to reflect that expenses for organ acquisitions for kidney transplants are an exception to the terms outlined in paragraphs (b) and (c), and will be covered

by original Medicare. Our new paragraph (d) generally tracks how section 17006(c) of the Cures Act amends section 1851(i)(3) of the Act.

The Cures Act does not provide for Medicare FFS coverage of organ acquisition costs for kidney transplants incurred by PACE participants. Therefore, PACE organizations must continue to cover organ acquisition costs for kidney transplants, consistent with the requirement described in section 1894(b)(1)(A)(i) of the Act that PACE organizations provide all Medicare-covered items and services. Accordingly, CMS will continue to include the costs for kidney acquisitions in PACE payment rates.

The following is a summary of the comments we received and our responses:

Comment: Several commenters expressed support for the implementation of this Cures Act requirement.

Response: We appreciate the commenters' support of our approach to implementing this change.

Comment: A commenter encouraged CMS to monitor the effects of the proposal's approach to organ acquisition costs.

Response: While we will continue to monitor and analyze the impact of this change, we must comply with the statutory requirement for FFS Medicare to cover kidney acquisition costs for MA beneficiaries.

Comment: A commenter noted that neither the proposed rule nor the calendar year 2021 Advance Notice, which was published on February 5, 2020, provided clear guidance on billing and reimbursement for organ acquisition costs. This commenter urged CMS to clarify whether these services are to be billed directly to Medicare Administrative Contractors (MACs) and paid directly to the providers involved, rather than being paid to MA plans for pass-through to

providers. The commenter also requested that CMS clarify which organ acquisition costs will be payable by FFS Medicare.

Response: We appreciate the commenter's request for further clarification. We want to emphasize that the payment changes for organ acquisition costs apply only to kidneys. Effective January 1, 2021, FFS Medicare will cover kidney acquisition costs for MA beneficiaries in accordance with the processes and guidance outlined in the Claims Processing Manual,¹⁷ CMS Pub. 100-04, chapter 3 and the Provider Reimbursement Manual,¹⁸ CMS Pub. 15-1, chapter 31. Hospitals currently bill MA claims to their respective MACs for processing as no-pay bills so that the MA inpatient days can be accumulated on the Provider Statistics & Reimbursement Report (PS&R) (report type 118). These no-pay bills must identify kidney acquisition costs using revenue code 081X and the hospital must track each MA kidney transplant. For instructions on billing for kidney acquisition costs, please refer to chapter 3, sections 90.1 through 90.1.3, of the Claims Processing Manual. For details on services included as kidney acquisition costs, please refer to chapter 31, section 3101, of the Provider Reimbursement Manual. The MA kidney transplants will be used in the numerator and denominator on the Medicare cost report to determine Medicare's share of kidney acquisition costs. Final payment will be made to the hospital through the Medicare cost report.

Comment: A commenter questioned how CMS addresses the difference between cadaveric organ acquisition and living donor organ donation in assessing kidney acquisition.

¹⁷ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912>

¹⁸ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>

Response: We appreciate the commenter's question. Please refer to the Provider Reimbursement Manual, CMS Pub. 15-1, chapter 31,¹⁸ for more information on provider reimbursement for the costs related to acquiring living donor organs and cadaveric donor organs.

After careful consideration of all comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the regulatory changes to § 422.322 to conform with the statutory amendments requiring FFS Medicare coverage of kidney acquisition costs for MA beneficiaries, effective January 1, 2021.

C. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853 of the Act to require that the Secretary's estimate of standardized costs for payments for organ acquisitions for kidney transplants be excluded from Medicare Advantage (MA) benchmarks and capitation rates, effective January 1, 2021. As amended, section 1853(k)(5) of the Act provides for the exclusion from the applicable amount and section 1853(n)(2) provides for the exclusion from the specified amount of the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under the Medicare statute (including expenses covered under section 1881(d) of the Act). As discussed in greater detail in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (hereinafter referred to as the April 2011 final rule) (76 FR 21431, 21484 through 21485) and the annual Advance Notices and Rate Announcements starting with Payment Year 2012,¹⁹ the applicable amount and the specified amount are used in the

¹⁹The Advance Notice and Rate Announcement for each year are available online at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>.

calculation of the MA benchmarks and capitation rates. We proposed to revise the relevant regulations to reflect these amendments.

Specifically, we proposed to revise § 422.258, which describes the calculation of MA benchmarks. Under section 1853(n)(1)(B) of the Act and § 422.258(d) of the regulations, for 2012 and subsequent years, the MA benchmark for a payment area for a year is equal to the amount specified in section 1853(n)(2) of the Act (that is, the “specified amount”), but, as described in section 1853(n)(4) of the Act and § 422.258(d)(2)(iii), cannot exceed the applicable amount specified in section 1853(k)(1) of the Act and § 422.258(d)(2). Prior to enactment of the Cures Act, section 1853(n)(2)(A) of the Act described the specified amount as the product of the base payment amount for an area for a year (adjusted to take into account the phase-out in the indirect costs of medical education from capitation rates) and the applicable percentage for the area and year. The base payment amount is, for years after 2012, the average FFS expenditure amount specified in § 422.306(b)(2). Section 17006(b)(2)(A) of the Cures Act amended section 1853(n)(2)(A)(i) of the Act to require that, for 2021 and subsequent years, the base payment amount used to calculate the specified amount must also be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate. We proposed to make conforming amendments to paragraphs (d)(3), (5), and (6) of § 422.258. As amended, paragraph (d)(3) would specify that for 2021 and subsequent years, the base payment amount used to calculate the specified amount is required to be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. Also, as amended, paragraphs (d)(5) and (6) would specify that the average FFS expenditure amount used to determine the applicable percentage is adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. To make these amendments, we proposed to insert

references to the adjustment made under § 422.306(d) to modify the various references to the base payment amount in paragraphs (d)(3), (d)(5), (d)(5)(i) and (ii), and (d)(6).

We proposed to amend § 422.306 by revising the introductory text and adding a new paragraph (d). Proposed paragraph (d) described the required adjustment, beginning for 2021, to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year. By operation of § 422.258(d)(2), the applicable amount is established by reference to § 422.306 and the rules there for calculation of MA annual capitation rates. By adding § 422.306(d), we would implement the new language in section 1853(k)(5) of the Act (added by section 17006(b)(1)(B) of the Cures Act) to require the adjustment to exclude payments for organ acquisitions for kidney transplants. We requested comment on whether these proposed revisions to §§ 422.258(d) and 422.306 adequately implement the statutory changes made by section 17006 of the Cures Act to require exclusion of the costs of kidney acquisition from the applicable amount and the specified amount for purposes of setting MA benchmarks and capitation rates.

Per section 1853(a)(1)(H) of the Act, CMS is required to establish separate rates of payment to an MA organization for individuals with end stage renal disease (ESRD) who are enrolled in a plan offered by that organization. This special rule for ESRD payment rates is codified in the regulations at 42 CFR 422.304(c). Since the Cures Act requires FFS Medicare payment for kidney acquisition costs for all MA enrollees, including MA enrollees with ESRD, we proposed to apply the exclusion of kidney acquisition costs to the ESRD payment rates. As § 422.304(c) does not prescribe the specific methodology CMS must use to determine the separate rates of payment for ESRD enrollees described in section 1853(a)(1)(H) of the Act, the

exclusion of kidney acquisition costs from ESRD rates does not require regulatory amendment. CMS addressed the methodology for excluding kidney acquisition costs from MA benchmarks (including the MA ESRD state rates) in the 2021 Advance Notice and Rate Announcement.

Section 1894(d)(2) of the Act requires that PACE capitation amounts be based upon MA payment rates established under section 1853 of the Act and adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. While capitated payments made to PACE organizations are based on the applicable amount under section 1853(k)(1) of the Act, we will include the costs for kidney acquisitions in PACE rates. Because PACE organizations are required to cover all Medicare-covered items and services under section 1894(b)(1)(A)(i) of the Act, including organ acquisition costs for kidney transplants, we will include kidney acquisition costs in PACE payment rates, including PACE ESRD rates. This approach is consistent with how PACE organizations have historically been paid for kidney acquisition costs for PACE enrollees. We did not propose any regulatory amendments to address this.

We appreciate commenters' feedback on our approach to implementing this Cures Act requirement. We received the following comments on our proposed regulatory changes, to which we provide responses below:

Comment: Numerous commenters expressed concerns about the methodologies for excluding kidney acquisition costs from MA benchmarks and for developing MA ESRD state rates. Several commenters requested additional transparency and data regarding the carve-out methodology, voiced concerns about the magnitude of the carve-out, and provided suggestions for alternative ways to calculate and apply the kidney acquisition adjustment. A commenter specifically noted that if the kidney acquisition carve-out amounts were to be artificially high,

excluding these costs from MA benchmarks would exacerbate the perceived issues of underpayment in MA for ESRD beneficiaries.

Response: Section 1853(b) provides for CMS to use the annual Advance Notice to provide notice of proposed changes to be made in the methodology for the MA capitation rates and risk adjustment factors from the methodology and assumptions used in the previous announcement. As discussed, the kidney acquisition carve-out is part of the methodology for developing the MA capitation rates. Pursuant to the statute, CMS proposed the methodology for calculating the kidney acquisition costs to be excluded from the MA benchmarks in the 2021 Advance Notice by providing a step-by-step description of the calculations to be used to adjust the rates. CMS also detailed in the calendar year 2021 Advance Notice the methodology used to develop ESRD state rates. After considering all public comments received and consistent with the statutory requirement to exclude the cost of kidney acquisitions for organ transplants from the primary components of the MA capitation rates, CMS finalized the kidney acquisition carve-out methodology, as well as the ESRD rate methodology, in the calendar year 2021 Rate Announcement. Similar comments regarding the need for transparency and accuracy in calculating the kidney acquisition cost, the methodology used by CMS, and the amount of payment to MA plans were raised in that context and addressed by CMS in the calendar year 2021 Rate Announcement. We direct readers to that document for a more detailed discussion of these issues.

Comment: A commenter requested that CMS explain whether the exclusion of kidney acquisition costs from MA benchmarks has an impact on Medicare-Medicaid Plans (MMPs).

Response: CMS develops annual Medicare capitation rates used for MMP payment. The MMP capitation rates are based on an estimate of what would have been spent in the payment

year had the demonstration not existed. Beneficiaries enroll in the MMP demonstrations from both MA and Medicare FFS, and therefore the MMP Medicare capitation rates are developed with a weighted average of these populations' spending assumptions, proportional to the combination of enrolled dually eligible beneficiaries. Therefore, the MMP Medicare capitation rates are developed using both the published Medicare standardized FFS county rates (which are part of the MA ratebook calculation files that are released with the annual Rate Announcement) and an MA component that is based on MA plans' bids and rebates.

As discussed in the calendar year 2021 Rate Announcement, kidney acquisition costs will be carved out of the contract year 2021 Medicare standardized FFS county rates. MA plans will bid against benchmarks that exclude kidney acquisition costs, in accordance with the statutory amendments to sections 1853(k) and (n); this is also consistent with how MA plans are no longer responsible for the costs of kidney acquisitions. Therefore, both components of the MMP Medicare capitation rate (the Medicare standardized FFS county rates and the MA component of the MMP rate) will exclude kidney acquisition costs. MMPs (like MA plans) will no longer be responsible for organ acquisition costs for kidney transplants; such costs will be excluded from the MMP rates and instead covered under Medicare FFS.

Comment: A commenter noted that plans will need to re-contract for transplant services to remove the cost of kidney acquisitions. This commenter explained that it is unlikely that the new contracts will carve out costs that are comparable to (or lower than) the costs being removed from the MA benchmarks. This commenter also requested the precise amounts CMS has paid on behalf on MA enrollees to each provider.

Response: We appreciate the commenter's concerns regarding this issue but must comply with the statutory requirement to exclude kidney acquisition costs from MA benchmarks. To

date, CMS has paid for kidney acquisition costs for MA beneficiaries through the county and ESRD state rates in the MA ratebooks.

Comment: Numerous commenters noted concerns about the adequacy and accuracy of the ESRD rates as well as the perceived underfunding of the underlying ESRD PPS. A few commenters also requested that CMS consider various options related to payment for dialysis services, including the establishment of a fee schedule cap for dialysis centers, implementation of zero cost sharing for dialysis services, and provision of an incentive payment for MA plans to offer home dialysis.

Response: As these comments did not address the impact, implementation, or consequences of the kidney acquisition carve-out required by the Cures Act, they are out of the scope of this rulemaking.

After careful consideration of all comments received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposed changes to § 422.258(d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) and the introductory text of § 422.306 and paragraph (d).

IV. Enhancements to the Part C and D Programs

A. Reinsurance Exceptions (§ 422.3)

Section 1855(b) of the Act requires MA organizations to assume full financial risk on a prospective basis for the provision of basic benefits (and, for plan years before 2006, additional benefits required under section 1854 of the Act) furnished to MA plan enrollees, subject to the exceptions listed in the statute at section 1855(b)(1)-(4) of the Act. The exception at section 1855(b)(1) of the Act states that an MA organization may obtain insurance or make arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds a per-enrollee aggregate level established by the Secretary. Section 1855(b)(1) of the Act describes stop loss insurance arrangements but we explained in the proposed rule that our proposal did not use those terms in order to be specific in describing the form of the arrangement. Section 1855(b)(1) of the Act permits an MA organization to obtain insurance or make other arrangements under which the MA organization bears less than full financial risk for the costs of providing basic benefits for an individual enrollee that exceed a certain threshold. In the proposed rule, we proposed to adopt a new § 422.3 to implement the exception at section 1855(b)(1) of the Act and establish in regulation options for MA organizations to use insurance for costs beyond a specified threshold. We proposed that an MA organization may obtain insurance (that is, reinsurance) or make other arrangements for the cost of providing basic benefits to an individual enrollee the aggregate value of which exceeds \$10,000 during a contract year or, alternatively, such costs may be shared proportionately on a first dollar basis, the value of which is calculated on an actuarially equivalent basis to the value of the insurance for costs that exceed \$10,000 in a contract year. We also proposed that if the MA organization chooses to purchase pro rata coverage that provides first dollar coverage, the value of that coverage cannot

exceed the value of the option of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of \$10,000 in a contract year. We noted in the proposed rule that the statutory exceptions at section 1855(b)(2) through (b)(4) of the Act still apply and that our proposal would serve to establish in regulation the threshold described in section 1855(b)(1) of the Act.

Because we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4), we proposed that the limits in § 422.3 apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits in excess of the established threshold and that those limits would not apply to supplemental benefits offered by MA organizations. We proposed to implement the exception at section 1855(b)(1) of the Act because of concerns raised to CMS that absent the implementation of specific standards by CMS under section 1855(b)(1) of the Act, there was ambiguity about the legal basis of MA organizations sharing risk through reinsurance. We noted in our proposed rule that a number of MA organizations expressed concern to CMS about this legal uncertainty as they have utilized reinsurance within the MA program. To resolve this uncertainty, we proposed to formally establish reinsurance standards implementing section 1855(b)(1) of the Act. Our proposal was generally not about subsections (b)(2) through (b)(4) of section 1855 of the Act.

Under our proposed implementation of the exception at section 1855(b)(1) of the Act, MA organizations that voluntarily choose to purchase insurance to limit their exposure to losses in furnishing basic benefits to individual enrollees would have two options. In the first option, an MA organization could purchase insurance (or make other arrangements) that would stop losses for the MA organization for individual plan enrollees when an individual enrollee's covered costs

for basic benefits exceed \$10,000 during a contract year. Stated another way, the MA organization could have insurance for costs that exceed \$10,000 for covering or furnishing basic benefits to an individual plan enrollee in the contract year. In the second option, an MA organization could purchase pro rata insurance coverage that would provide first dollar coverage provided that the value of the insured risk is actuarially equivalent to costs that exceed \$10,000 and the insurance coverage is priced at an actuarial value not to exceed the value of the stop loss insurance for medical expenses exceeding \$10,000 per member per year. Specifically, the value of first dollar pro rata insurance could not exceed the value of \$10,000 per member per year stop loss insurance.

In the proposed rule, we noted that in discussions with the National Association of Insurance Commissioners (NAIC) and in 2018 Call Letter comments we previously received, CMS was advised that the use of insurance by health care insurers is a common and long standing market practice for both commercial health insurers and MA organizations and that the practice has the purpose of reducing financial exposure to changes in health care costs, helps manage capital requirements, and allows health care insurers to grow enrollment. As we explained in our proposed rule, discussions with the NAIC and earlier information we received from the industry indicated that MA organizations located in areas with fewer beneficiary choices (for example, rural, underserved areas) particularly benefit from access to reinsurance because of how it provides financial stability for the MA organization, which in turn can lead to enhanced competition and consumer choice, especially in small and mid-sized market areas. Insuring part of the risk assumed under an MA plan is important for smaller MA organizations to compete with larger organizations that can independently finance their operations.

We also noted that excessive reinsurance can be viewed as a hazard to the extent that the direct health insurer (here, the MA organization) might pass such a large share of their risk and premium through insurance and that the MA organization could then be viewed as no longer possessing the primary responsibility for furnishing the health care services. We further explained in our proposed rule that while the statute identifies the category of risk for which an MA organization may seek insurance or other arrangements (such as, in section 1855(b)(1) of the Act, the cost of providing to any enrolled member such services the aggregate value of which exceeds an established threshold), it is in the context of a mandate that MA organizations assume full financial risk on a prospective basis for providing basic benefits to enrollees. We stated that we are cognizant of the need to ensure that MA organizations are not transferring all the risk of providing services to enrollees to a third party that is not under contract with CMS. We also stated that we seek to balance these different interests in setting the threshold for the individual stop loss insurance coverage authorized by the statute.

We also explained that the \$10,000 threshold we proposed has its roots in our review of the Conference Report for the BBA of 1997 (H.R. Conf. Rep. 105-217) and the difference between the House bill and the Senate amendment on the threshold at which a Part C plan could reinsure per-enrollee costs. The Conference Report indicates that the House bill tracked existing language in section 1876(b)(2)(D)(i) of the Act in using a \$5,000 per year threshold while the Senate amendment provided for an amount established by the agency with an annual adjustment using the Consumer Price Index-Urban (CPI-U) for the 12-month period ending with June of the previous year. The conference agreement was to adopt the language in section 1855(b)(1) of the Act that remains today: A threshold established by the agency from time to time. To develop the \$10,000 threshold we are proposing, we started with the amount of \$5,000 identified in the

Conference Report and used the following methodology: We multiplied the amount identified in the Conference Report (\$5,000) by the increase in the CPI-U. Our policy choice was heavily influenced by the description in the Conference Report of the Senate amendment: “the applicable amount of insurance for 1998 is the amount established by the Secretary and for 1999 and any succeeding year, is the amount in effect for the previous year increased by the percentage change in the CPI-urban for the 12-month period ending with June of the previous year.” In updating the threshold this way, we rounded the amount for each year to the nearest whole dollar. Actual CPI-U values through June 2019 were used to perform these calculations. After 2019, the CPI-U values are estimated using the Congressional Budget Office's August 2019 report: An Update to the Economic Outlook: 2019 to 2029.

In our discussion, we stated that based on a scan of the market and current practices of commercial health insurers, we believed that the \$10,000 threshold for stop loss insurance that we proposed reflected a level of risk transfer that was reasonable and consistent with supporting robust competition in Medicare Advantage. We also explained our position that the proposed level of risk transfer would be acceptable given that CMS closely monitors MA organizations in terms of their administration of their MA plans, specifically their timely provision of medically necessary health care services to enrollees and their overall financial solvency. We further clarified that CMS has a direct contract with each MA organization and despite any insurance arrangements, the MA organization remains responsible and liable to each individual enrollee for furnishing the covered benefits. In addition, we explained that CMS through its regional offices, plan audits, review of enrollee appeals and stakeholder letters closely monitors the performance of MA organizations and intervenes whenever it has evidence an MA organization is not meeting its contractual obligations. We also noted that any insurance arrangement used by MA

organizations is subject to state insurance regulation and oversight regarding solvency because section 1856(b)(3) of the Act does not preempt those solvency laws or provide that CMS regulation supersedes them. We noted our understanding that the NAIC model laws (Model 785); NAIC Credit for Reinsurance Regulation (Model 786); and the NAIC Life and Health Reinsurance Agreements Model Regulation (Model 791) have been substantially adopted by all states. We believe the wide adoption of the NAIC reinsurance model laws by states ensures reasonable consistency for MA organizations subject to reinsurance review as part of the state's financial solvency determination. Finally, we stated that CMS oversight along with the states' oversight of financial solvency substantially would ensure that CMS would be able to intervene on a timely basis when an MA organization is experiencing solvency problems or is not meeting its obligation to appropriately furnish its enrollees with benefits covered under the MA plan.

We also acknowledged that the reinsurance marketplace is complex and evolving. Therefore, we asked for comments regarding our proposed reinsurance regulation generally and the specific threshold proposed. We stated that we were particularly interested in comments whether the \$10,000 threshold is a reasonable level and if the flexibility we proposed for MA organizations in permitting insurance or other arrangements that are actuarially equivalent to the \$10,000 threshold for individual medical costs is sufficient to remove the uncertainty about the use of reinsurance by MA organizations. We also solicited comments that would provide additional information about insurance or other arrangements for addressing the risk of costs that exceed specific thresholds on an individual enrollee basis.

In our proposed rule, we also explained that we would consider an MA organization to include its parent organization when evaluating compliance with the proposed standard for reinsurance and compliance with the statute. The result of that would be to evaluate compliance

with section 1855(b) of the Act (not just subsection (b)(1)) and proposed § 422.3 at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries would not be evaluated. We requested comments on this approach and whether CMS should consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act or whether CMS should consider a parent organization to be a separate entity from an MA organization.

We thank commenters. We received 13 comments on this proposal; we summarize these comments and our responses follow:

Comment: Several commenters were generally supportive of § 422.3(a)(1) affirming the ability of MA organizations to purchase stop loss insurance for basic Medicare covered medical expenses for an individual enrollee that exceed with an aggregate value of \$10,000 or more per member per year in any year. However, several commenters expressed concerns about the proposed pro rata insurance requirement at § 422.3(a)(2), requiring that this option not exceed the actuarial cost of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of \$10,000 in a contract year. A commenter stated that they read the proposed regulation as requiring that the value of the insured risk does not exceed a value which is actuarially equivalent to the aggregate value of the costs of providing basic benefits to an individual enrollee which exceeds an aggregate level that is greater than or equal to \$10,000 during a contract year. The commenter said that they found this language difficult to follow. This commenter also said that, further complicating the matter, excess of loss insurance (that is, stop loss) and first dollar proportional (that is, pro rata) insurance are very different forms of reinsurance. Other commenters were also concerned that because of the differences in these types of insurance it would be difficult calculating an actuarial value for the cost of purchasing

annual pro rata insurance, which shares costs with an insurer on a first dollar proportional basis. The commenters also said that their uncertainty about how to calculate this actuarial equivalency would make it difficult for them to ensure they would be in compliance with the proposed regulatory requirement. Several commenters recommended that instead of an actuarial equivalence that we set a limit on the amount of risk that an MA organization would be allowed to transfer to a reinsurer. Several commenters specifically proposed that CMS adopt a 10 percent standard under which an MA organization would be required to maintain a minimum of 10 percent of the financial risk in any reinsurance arrangement involving the sharing of costs proportionately with an insurer on a pro rata first dollar basis.

Response: We agree that the reinsurance options under proposed § 422.3(a)(1) and (2) are different and acknowledge this potentially creates uncertainty and difficulties in determining actuarial equivalency, as pointed out by the commenters. As we noted above the statute permits an MA organization to use insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee that exceed a certain threshold. In order to provide an option for using insurance or other arrangements for some of the cost of providing basic benefits to an individual enrollee before the threshold is exceeded, we sought to establish a way to equate the \$10,000 stop loss threshold to sharing the risk proportionally on a first dollar basis (that is, pro rata insurance) to provide additional flexibility to MA organizations while ensuring compliance with the statute.

In considering these comments we appreciate that there could be difficulty for some organizations in determining whether and when the two reinsurance options were actuarially equivalent or in determining an actuarially equivalent dollar amount for the two reinsurance options. We also recognize that it would be administratively simpler if we were to adopt a single

standard for the amount of risk an MA organization can transfer to an insurer under this regulation. As we discuss below we are finalizing regulation text to clarify how MA organizations can make an actuarial equivalency determination between the \$10,000 stop loss insurance option and the option to purchase first dollar proportional (that is, pro rata) insurance. In addition, we have determined that the ability to purchase pro rata insurance affords the MA organizations the necessary flexibility to purchase different types of reinsurance. We are specifically finalizing this regulation to allow an MA organization to have insurance or make another arrangement for the cost of providing basic benefit to an enrollee, the aggregate value of which exceed an aggregate value that is equal to or greater than \$10,000. In effect, an MA organization can have stop-loss insurance per enrollee with a \$10,000 attachment point. In addition, the MA organization may use insurance to share costs proportionately on a per member per year first dollar basis as long as the amount of risk retained by the MA organization is actuarially equivalent to the risk retained in purchasing \$10,000 per member per year first dollar stop loss insurance. To specifically address the concerns about actuarial equivalence valuations we have determined that actuarial equivalence may be calculated as the expected percentage of the MA organization's claim cost of providing basic benefits to an individual enrollee that is greater than or equal to \$10,000 during a contract year. The MA organization may share its costs proportionately on a first dollar basis up to the expected percentage. For example, assume that the actuarially supported expected percentage is 66 percent. In this example, the MA organization may reinsure (cede) up to 66 percent of such costs proportionately on a first dollar basis. However, we recognize that there are other reasonable actuarial approaches that could be used to determine the actuarial equivalence cost when purchasing pro rata insurance. We will accept approaches that are based on a reasonable actuarial methodology. An MA organization

may also value its pro rata insurance by establishing a specific percentage level of risk that it can reinsure that is not more than the actuarial value of \$10,000 individual stop loss insurance.

Appreciating that some commenters indicated that the proposed regulation text describing the permissible stop-loss arrangement was confusing, we are clarifying this in the final regulation text. The regulation now states the permissible insurance or other arrangement by describing the permissible reinsurance or other arrangement in terms of how much and which financial risk the MA organization must retain: the MA organization must retain the risk for at least the first \$10,000 in costs of providing basic benefits per individual enrollee during the contract year.

To specifically address the concerns about actuarial equivalence valuations, we are finalizing regulation text to clarify that MA organization may make a determination of actuarial equivalence based on reasonable actuarial methods. We are finalizing that an MA organization may share the costs of providing basic benefits on a per member per year first dollar basis when: (i) the actuarial value of the risk retained by the MA organization is actuarially equivalent to the value of the risk that must be retained using the permissible stop-loss arrangement that is described in paragraph (a)(1) and (ii) the determination of actuarial equivalence is based on reasonable actuarial methods. For example, actuarial equivalence may be reasonably calculated using the expected percentage of the MA organization's claim cost of providing basic benefits to an individual enrollee that is greater than or equal to \$10,000 during a contract year. The MA organization may share its costs proportionately on a first dollar basis up to that expected percentage. For example, assume that the actuarially supported expected percentage is 66 percent. In this example, the MA organization may reinsure (cede) up to 66 percent of such costs proportionately on a first dollar basis. However, we recognize that there are other reasonable actuarial approaches that could be used to determine the actuarial equivalence cost

when purchasing pro rata insurance. We will accept approaches that are based on a reasonable actuarial methodology. An MA organization may also value its pro rata insurance by establishing a specific percentage level of risk that it can reinsure that is not more than the actuarial value of \$10,000 individual stop loss insurance.

Comment: Several commenters asked for clarification about the applicability of the proposed reinsurance rule, asking if it would apply to quota share reinsurance arrangements under section 1855(b)(1) of the Act alone, or will it also apply to quota share reinsurance arrangements under subsections (b)(2), (b)(3) and (b)(4) of section 1855 of the Act as well. The commenters wanted to know if quota share arrangements would be permissible only in the specific circumstances described in our proposed rule to implement section 1855(b)(1) of the Act.

Response: Our proposal and this final rule at § 422.3(a) are specifically about implementing section 1855(b)(1) of the Act. Section 1855(b)(1) permits MA organizations to insure or make other arrangements for the cost of providing to any enrolled member basic benefits the aggregate value of which exceed a threshold set by the agency. We proposed that threshold (\$10,000) and a way that MA organizations could share *that particular risk* proportionately by tying the parameters for the proportionate-risk arrangement to the actuarial value of the financial risk where the stop loss threshold is over \$10,000.

MA organizations are only permitted to share risk proportionally so long as the risk (the type and amount) is in the statutory exceptions at section 1855(b) of the Act. Section 1855(b) of the Act describes types of risk for which an MA organization may use insurance or make other arrangements. For example, section 1855(b)(2) permits an MA organization to obtain insurance or make other arrangements for the cost of basic benefits provided to its enrollees other than

through the organization because medical necessity required the provision of those basic benefits before that organization could furnish them; an MA organization could use insurance to cover all of the costs described in subsection (b)(2), use a quota share arrangement for those costs, or use some other reinsurance arrangement for those costs. However, section 1855(b)(2) only permits the use of reinsurance or risk sharing arrangements for those specifically described costs. Our proposal and this final rule at § 422.3(a) do not address the other statutory exceptions at section 1855(b) of the Act.

Comment: Several comments asked that CMS acknowledge that CMS policy has, in the past, permitted MA organizations to utilize quota share reinsurance arrangements with captive insurance companies and risk bearing entities including provider-affiliated captive insurance companies, or other risk-bearing entities under the authority of section 1855(b)(4) of the Act, and that CMS will continue to allow this. Commenters also asked that CMS further clarify whether the provider-affiliated entity must be wholly-owned by the provider, or whether a lower percentage of ownership is required.

Response: Section 1855(b)(4) of the Act permits an MA organization to make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for basic benefits furnished by such physicians, by such other health professionals or through such institutions. The type of payment arrangement used between the MA organization and contracting physicians, other health professionals or institutions for this specified financial risk is not limited by § 422.3(a). To be clear on this point, we are finalizing § 422.3(c) to state that the type of payment arrangement between an MA organization and contracting physicians, other health professionals or institutions for the financial risk on a

prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by § 422.3(a).

Comment: Two commenters asked if reinsurance options under §422.3(a)(1) and (2) can also include MA supplemental benefits. A commenter stated that it is operationally very challenging to separate the revenues and expenses associated with supplemental benefits from the revenues and expenses associated with basic benefits.

Response: As we stated in the proposed rule, we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4). The limits in proposed § 422.3(a) and finalized in this rule apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits and therefore do not apply to supplemental benefits offered by MA organizations. MA organizations are not prohibited from obtaining reinsurance for supplemental benefits and this final rule does not limit either the form or amount of reinsurance for supplemental benefits.

Comment: Commenters were supportive of our proposal with respect to section 1855(b) to broaden our interpretation of MA organization to include the parent organization. This would mean that CMS would evaluate compliance with 1855(b) of the Act and proposed §422.3 at the parent organization level, such that risk sharing or allocations MAO of losses and costs among wholly-owned subsidiaries would not be evaluated. Commenters also asked if CMS will accommodate situations where an MA organization obtains reinsurance from captive insurance companies, an affiliate and/or a joint venture or alliance partner. A commenter noted that reinsurance is a useful means by which to share profits/losses in joint ventures and alliances, an entity may choose to allocate its risk to a reinsurer that is an affiliate of the MA organization and

to another joint venture or alliance partner. The comment states that these arrangements serve as a mechanism to facilitate the allocation of profits/losses under a joint venture or alliance.

Response: In this final rule we are affirming that for purposes of 1855(b) of the Act and for § 422.3, we will evaluate compliance at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries will not be evaluated. These internal arrangements would be treated as the MA organization retaining full financial risk for the losses or risks that are covered through the internal arrangement. We are adding language to the final regulation at §422.3(b) confirming this position. Reinsurance arrangements facilitated for purposes of joint venture and alliance partner must comply with 1855(b) of the Act, CMS regulations and requirements, other federal laws and regulations, and state laws and requirements.

We thank the commenters for sharing their concerns and recommendations regarding our proposed implementation of Section 1855(b)(1) in the MA regulations at § 422.3. After careful examination of all comments received and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing § 422.3 with modifications from the proposal. As finalized, paragraph (a) provides that an MAO may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee during the contract year in one of two ways. We are finalizing § 422.3(a)(1) to permit an MA organization to use insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee during the contract year so long as the MA organization retains risk for at least the first \$10,000 of that cost. We are finalizing § 422.3(a)(2)(i) permitting reinsurance on a per member per year first dollar basis so long as the MA organization retains at least an amount of risk that is actuarially equivalent to the value of risk retained in paragraph (a)(1). We also clarify in the final regulation

at §422.3(a)(2)(ii) that MA organizations obtaining such reinsurance under the option described at §422.3(a)(2)(i) may utilize any reasonable actuarial methodology to determine actuarial equivalence.

We are also adding § 422.3(b) clarifying that CMS will consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act. Finally, we are adding regulation text at § 422.3(c) to clarify the type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act is not limited by paragraph (a).

B. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. CMS must propose through rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures. Sections 422.164(e) and 423.184(e) provide authority and a mechanism for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the measure change such that the specifications are no longer believed to align with positive health outcomes). In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of

Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codified a policy to adjust Star Ratings for disasters, and finalized some measure updates. In the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule (85 FR 19230; CMS-1744-IFC) published in the Federal Register website on April 6, 2020, CMS adopted a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID-19 pandemic. Specifically, the IFC:

- Eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data otherwise collected in 2020 and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the public health threats posed by COVID-19);
- Establishes how we will calculate or assign Star Ratings for 2021 in the event that CMS's functions become focused on only continued performance of essential agency functions and the agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings;
- Modifies the current rules for the 2021 Star Ratings to replace any measure that has a systemic data quality issue for all plans due to the COVID-19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- In the event that we are unable to complete Health Outcomes Survey (HOS) data collection in 2020 (for the 2022 Star Ratings), replaces the measures calculated based on

HOS data collections with earlier values that are not affected by the public health threats posed by COVID-19 for the 2022 Star Ratings;

- Removes guardrails for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;
- Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and
- Revises the definition of “new MA plan” so that for purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings will be based in part on data for the 2018 performance period.

Please see the IFC for further information on these changes for the 2021 and 2022 Star Ratings.

In the February 2020 proposed rule, we proposed enhancements to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. We also proposed to increase the weight of patient experience/complaints measures and access measures and remove the Rheumatoid Arthritis Management (Part C) measure from the Star Ratings because the measure steward is retiring the measure from the HEDIS measurement set. We proposed to modify the classification of the Statin Use in Persons with Diabetes (SUPD) measure from an intermediate outcome measure to a process measure, starting with the 2023 Star Ratings, due to feedback in response to the Draft 2020 Call Letter and to align with the measure steward’s clarification regarding the measure’s classification. In addition, we proposed other policies to amend the Part C and Part D Star

Ratings but are not addressing those proposals in this final rule; those other proposals will be addressed in a future final rule.

Our proposal was for the changes we address here – the removal of outliers, increasing the weight of certain classes of measures, removing the Rheumatoid Arthritis Management measure, and reclassifying the SUPD measure – to be effective for the 2021 performance period and the 2023 Star Ratings. As discussed in this section, we are finalizing the proposed changes with some modifications. As finalized, the change to the weight of the patient experience/complaints measures and access measures, the removal of the Rheumatoid Arthritis Management measure, and the reclassification of the SUPD measure are applicable (that is, data would be collected and performance measured) for the 2021 measurement period and the 2023 Star Ratings. Under this final rule the direct removal of outliers will apply for the 2022 measurement period and the 2024 Star Ratings.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. Below we summarize some general comments we received about the potential impact of the COVID-19 public health emergency on our Star Ratings proposals.

Comment: Numerous commenters requested that CMS refrain from making any changes to the Star Ratings system until the COVID-19 pandemic's impact on the healthcare system is better understood. They suggested we delay any changes to the quality rating system until after the public health emergency resulting from COVID-19 subsides due to the significant uncertainties around the duration and impact of COVID-19 on the health care system.

Response: CMS agrees that there is a lot of uncertainty about how COVID-19 will impact the healthcare system. However, we still believe that it is important to move forward with some

limited Star Ratings changes to further emphasize the importance of patient experience/complaints measures and access measures and to help stabilize the movement in the cut points from year to year. The changes to the weighting of patient experience/complaints measures and access measures apply to the 2021 measurement year, not the 2020 measurement year when the pandemic first started. The implementation of Tukey outlier deletion has been delayed an additional year. Although there is some uncertainty how COVID-19 will impact the healthcare system and quality measurement, plans will have until the 2021 measurement year to adjust their processes to account for the impact of COVID-19 on Star Ratings measures.

Comment: Commenters raised concerns that additional Star Ratings changes may be needed to account for COVID-19 in future years. For example, several commenters noted data collection challenges could impact 2021, 2022, 2023, and 2024 Star Ratings for some measures. A commenter noted COVID-19 may overwhelm our healthcare systems leading to significant impacts on many measures. A few commenters specifically noted concerns about supply chain disruptions and prescription drug shortages. A commenter noted that plan activities in response to emergency situations can create unintended consequences in the years following, including for Star Ratings. Another commenter suggested CMS revisit the capacity and capability expectations defined in specific measures and meet with provider and plan stakeholders when the crisis has abated; they suggest some measures may need to be re-tooled so that scarce resources are devoted to building capacity and functionality of the health and social delivery systems.

Response: CMS is continuing to monitor the situation to see if additional Star Ratings changes are necessary and appropriate. As noted above, the IFC includes a series of changes for the 2021 and 2022 Star Ratings to accommodate challenges arising from the COVID-19 pandemic. Please see the IFC for further information on these changes for the 2021 and 2022

Star Ratings. CMS recognizes that there may be impacts from COVID-19 on measure scores and is delaying the implementation of Tukey outlier deletion for an additional year to allow these impacts to play out before adding an additional methodological change for the cut point calculations.

Comment: A commenter asked that CMS remain cautious on pursuing changes that could weaken the ability of plans to make quality improvements in the aftermath of COVID-19.

Response: CMS recognizes the challenges that COVID-19 has placed on the healthcare system and Part C and Part D plans that are subject to the Quality Star Rating System. CMS continues to monitor whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter requested that CMS ensure that policy changes that allow pharmacies to meet prescription drug therapy needs during the COVID-19 outbreak are not used to penalize pharmacies in their performance ratings.

Response: CMS will continue to monitor the impact of COVID-19 on the healthcare system. The Part C and D Star Ratings are for rating the Medicare health and drug plans not pharmacies.

Comment: Several commenters noted that different areas of the country may experience the pandemic differently, and there may also be differences by health plan populations, such as those with high dual eligible or low-income populations. A commenter noted that CDC's recommendation for social distancing, especially for more vulnerable populations, may result in Medicare beneficiaries not pursuing preventive screenings, and that this may be more impactful for beneficiaries in geographies more heavily impacted by COVID-19 and for beneficiaries in rural areas with less access to care.

Response: CMS will continue to monitor the impact of COVID-19 on the healthcare system and Part C and D plans. The IFC addressed the immediate impact of the pandemic on the Part C and D Star Ratings program and made additional modifications for the 2022 Star Ratings, in recognition that the COVID-19 pandemic may impact performance on the Star Ratings measures during the 2020 measurement period. CMS delayed the implementation of guardrails to allow cut points to adjust to changes in industry performance for the 2020 measurement period. Additionally, CMS expanded the hold harmless provisions for the Part C and D improvement measures that are based on the 2020 measurement period so that those measures where there is a significant decrease in performance will not bring down a contract's overall or summary ratings for the 2022 Star Ratings. CMS continues to monitor to what extent our current policy for extreme and uncontrollable circumstances codified at §§ 422.166(i) and 423.186(i) will help address the issue of some geographic areas being more impacted than others and whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter asked that CMS consider the longer-term economic ramifications that COVID-19 is causing to highly impacted areas when considering Star Ratings policies.

Response: CMS will continue to monitor the impact of COVID-19 on the healthcare system and Part C and Part D plans that are subject to the Quality Star Rating System. CMS continues to monitor whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter suggested that given the strain COVID-19 is placing on the healthcare system, CMS should suspend Effectiveness of Care measures based on 2020 data. Another asked whether the Part D appeals measures would still be removed for 2021.

Response: Generally, these comments are out of the scope of the proposed rule and the policies we are addressing in this final rule. The IFC addressed the immediate implications of the pandemic on the Part C and D Star Ratings program. Specifically, for the 2020 measurement year, it delays the implementation of guardrails so cut points will adjust downward if industry performance broadly declines as a result of the pandemic. CMS is proceeding to remove the Part D appeals measures for the 2020 measurement year and the associated 2022 Star Ratings, as outlined in the 2020 final Call Letter, under § 423.184(e)(1) and based on our determination that the measure is no longer reliable.

Comment: Several commenters gave specific feedback related to the IFC and the 2021 and 2022 Star Ratings.

Response: We thank commenters for this feedback, but these comments are out of scope for this rule. We will discuss comments to the IFC policies in a future final rule.

2. Measure-level Star Ratings (§§ 422.166(a), 423.186(a))

Over the past 2 years, we have codified and refined the methodology for calculating the Star Ratings from the performance scores for non-CAHPS measures. At §§ 422.166(a) and 423.186(a), we initially codified the historical methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data from the most recent Star Ratings year; therefore, the cut points are sensitive to changes in performance from 1 year to the next.

The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories or groups such that each grouping accurately reflects true performance. The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. We solicited comments in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule (hereinafter referred to as the November 2017 proposed rule) regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Benefit, Programs for All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (hereinafter referred to as the November 2018 proposed rule). In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the November 2018 proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for cut points that included stability, predictability, and attenuation of the influence of outliers; commenters also suggested restricting movement of cut points from one year to the next and recommended that CMS either pre-announce cut points before the plan preview period or pre-determine cut points before the

start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology while maintaining the intent of the cut point methodology to accurately reflect true performance.

Using the feedback from the comments we received in response to the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. The IFC (CMS-1744-IFC) delays the implementation of guardrails for an additional year; thus, it will be implemented for the 2021 measurement year and the 2023 Star Ratings.

Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule in order to provide the public prior notice of a proposal for incorporating removal of outliers and an opportunity to comment on a specific approach and so that we could continue to evaluate the methodologies for outlier removal (84 FR 15761).

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the

99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether such scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

In the February 2020 proposed rule, we proposed to use Tukey outer fence outlier deletion as the method to identify and delete outliers before applying the already-applicable mean resampling and hierarchical clustering processes. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point or above a certain point. We proposed that the lower point or the "lower outer fence" would be identified with this formula: $(\text{first quartile} - 3.0 \times (\text{third quartile} - \text{first quartile}))$; and the higher point or the "upper outer fence" would be identified with this formula: $(\text{third quartile} + 3.0 \times (\text{third quartile} - \text{first quartile}))$. The Tukey outer fence outlier deletion will remove all outliers based on the previous definition for the two points (that is, the lower and upper outer fences) and does not remove any cases that are not identified as outliers. Values identified as outside the Tukey outer fences would then be removed immediately prior to clustering.

We explained in the proposed rule that if Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA-PD

contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment, because these measures will be removed starting with the 2022 Star Ratings. In general, there tends to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

We requested comments on our proposal to use Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. We explained that under our proposal in the first year of implementing this process, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We proposed to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology ("Tukey outer fence outliers") and to amend §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering.

We received the following comments related to our proposal, and our responses follow:

Comment: Most commenters opposed moving forward with the Tukey outlier deletion at this time, citing a variety of different reasons. A handful of commenters raised general concerns about the Tukey outlier deletion method, mentioning criticism in academic communities about applying Tukey fences to skewed data, given what the commenters characterized as the Tukey approach's assumption of a normal distribution. Other commenters suggested additional

research is needed on alternatives for removing outliers. Some commenters did not support the use of Tukey outlier deletion without more information about how the Tukey outlier fence models will be applied and more detail on CMS analyses. A couple of commenters did not support adding Tukey outlier deletion given the fluctuation it may cause in the ratings.

Response: CMS is concerned about extreme outliers influencing cut point determinations and has selected an approach to identify and remove outliers prior to clustering contract scores to determine cut points for assigning measure stars. The main objective of removing outliers is to stabilize cut points and prevent large year-to-year fluctuations in cut points caused by the scores of a few contracts. CMS selected the conservative outer-fence form of the Tukey outlier deletion method because it is transparent (easily understood and can be implemented by stakeholders with widely-available software) and robust to distributional shape (it performs as intended for this purpose across the range of score distributions seen in Star Ratings data).

CMS disagrees that the Tukey outer fence outlier approach is inappropriate for identifying the outliers to be removed from the performance score data. Even when the data are not normally distributed (for example, in a skewed distribution), the Tukey approach performs as intended. The Tukey outer fence outlier deletion approach is a standard statistical method that is non-parametric, that is, it is not dependent on distributional assumptions. We plan to adopt a more conservative definition, based on Tukey *outer* fences, that only removes scores that are extreme outliers. This approach removes fewer outliers at both extremes of the score distribution than the inner fence approach. We plan to identify and remove extreme outliers immediately prior to applying the clustering algorithm to set cut points. The Tukey outer fences would be calculated from the set of measure scores after removing contracts that are to be excluded from clustering (such as because the measure is voluntary for that contract).

The first step in applying the Tukey outlier deletion method is calculating the first quartile (Q1) and third quartile (Q3) of the score distribution: 25 percent of scores fall below Q1, another 25 percent of scores fall above Q3, and the remaining 50 percent of scores fall between Q1 and Q3. Next, we calculate the interquartile range (IQR), the difference between the third and first quartiles ($IQR=Q3-Q1$), which refers to the range of the middle 50 percent of all scores. The Tukey outer fence method identifies extreme outlier as those that are below ($Q1 - 3 \times IQR$) or above ($Q3 + 3 \times IQR$).

We examined the use of trimming as an alternative outlier removal approach and found very similar results as those described in the proposed rule from using the Tukey approach. We performed simulations that trimmed any scores that were above the 99th percentile or below the 1st percentile, trimming values at the tail ends of the distribution prior to clustering. The method had effects on Star Ratings similar to those of the Tukey method. An important strength of the Tukey outer fence outlier deletion method over the trimming method is that trimming removes a fixed proportion of plan scores for each measure, regardless of whether those scores are distant from the center of the score distribution. In contrast, the Tukey outer fence method removes only true outliers that are the most distant from the center of scores.

Comment: Some commenters suggested alternatives to outlier deletion to help improve the stability of cut points. A commenter suggested that CMS might consider cut points using plans in similar geographic areas with similar characteristics. Another suggested CMS explore other classification methods such as Isolation Forest, DBSCAN, or k-means clustering. A couple of commenters recommended a guardrail cap less than 5 percent.

Response: CMS agrees that stability is a goal for the cut points, but we disagree with the recommendations of the commenters to achieve that stability. Setting regional or geographic

benchmarks (cut points) would lead to a 5-star contract in one area differing in terms of performance from a 5-star contract in another area. The Medicare program does not set regional standards, but rather applies a single national standard to evaluate plan performance. As required under section 1851(d), CMS disseminates information to Medicare beneficiaries (and prospective Medicare beneficiaries) on the different coverage options to promote an active, informed selection among such options. This includes plan quality and performance indicators to compare plan options. In order to compare in a consistent way, CMS uses a single national standard since different regional cut points could hide deficiencies in different areas. Additionally, many measures are based on compliance with Medicare rules and requirements (for example, call center measures and appeals measures) and reflect compliance with Medicare program requirements, not comparative compliance. Using regional cut points would warp the results and complicate our use of Star Ratings under §§ 422.504(a)(17), 422.510(a)(4)(ix), 423.505(a)(26), and 423.509(a)(4)(x).

Regarding the choice of clustering method, hierarchical clustering is one of the most commonly used methods for clustering observations into groups. There are pros and cons of all methods for clustering, including those identified by the commenters. We have considered other methods and believe hierarchical clustering is the best option for the Part C and D Star Ratings program because it is well understood, easily implemented, and performs well for a variety of different data distributions. The other very commonly used clustering algorithm is k-means, however one key weakness of that approach is that the final set of clusters depends on the initial random assignment of points to clusters and it is highly sensitive to the initial placement of cluster centers. Specifically, when the algorithm is repeated on the same dataset it may result in different cluster assignments. Additionally, the k-means method is sensitive to outliers (for

example, Gan and Ng (2017)²⁰, Govender and Sivakumar (2020)²¹), and therefore it would not resolve the issue that outliers can influence estimated thresholds. The commenter also noted other clustering algorithms that are less commonly used. For example, weaknesses of DBSCAN include sensitivity to parameters and inability to handle clusters of points of varying densities, which makes DBSCAN less attractive for clustering measure scores. Isolation Forest is an outlier or anomaly detection technique on the basis of decision trees that is not directly related to clustering measure scores into 5 groups.

Comment: A couple of commenters opposed Tukey outlier deletion since they were concerned it would make it harder for plans with more complex populations to perform well, including SNP plans. A commenter noted the current national emergency emphasizes the need for the cut point methodology to separate out plans with high proportions of dually-eligible, disabled, and low-income individuals.

Response: The issues of whether it is harder for plans with complex populations to perform well in Star Ratings and the method by which we stabilize thresholds for cut points are unrelated. The strategy of removing outliers for stability of cut points does not affect how performance is compared across plans with and without complex populations.

In simulations of Star Ratings calculated using the Tukey outer fence outlier approach, we found that the effect of outlier removal on SNP versus non-SNP contracts was not very different. When outlier measure scores were removed as a part of our simulation using the data for the 2018 Star Ratings, overall summary ratings shifted from 4 to 3.5 stars for approximately 4

²⁰ Gan, G., & Ng, M.K. (2017). K-means Clustering with Outlier Removal. *Pattern Recognit. Lett.*, 90, 8-14.

²¹ Govender, P. & Sivakumar, V. (2020). Application of k-means and hierarchical clustering techniques for analysis of air pollution: A review (1980–2019). *Atmospheric Pollution Research*. 11(1), 40-56.

percent of contracts without a SNP, and for about 5 percent of contracts with a SNP for the contracts with overall ratings. The removal of outliers will not necessarily have consistent year-to-year impacts, and is dependent on where contracts fall in the measure score distributions, with contracts near the bottom of a score range being the most likely affected.

CMS adopted the categorical adjustment index (CAI) to address the concern that plans with more complex populations have lower ratings based on the population served under the contract. The CAI advances more equitable plan comparisons because it generates Star Ratings that contracts would have received if they had all served the same patient population. That is, the CAI adjusts for within-contract disparities based on measures that are not otherwise adjusted for patient characteristics. CAI coefficients are estimated each year so if there is a differential impact of COVID-19 on the measures of performance for contracts with a higher percentage of dual eligible and disabled beneficiaries versus contracts with a lower percentage of enrollees with those social risk factors, the CAI values would reflect these differences. The CAI will continue to adjust for the percentage of LIS/DE and disabled beneficiaries within the contract in accordance with §§ 422.166(f)(2) and 423.186(f)(2), and therefore will adjust for these differences for contracts with and without a SNP.

Comment: A commenter suggested that CMS retire measures from the program when there are one percentage point differences in the same direction between cut points year over year.

Response: CMS does not consider the size of changes in performance from year-to-year to be a criterion for retirement of a measure, particularly when there is still room for improvement on the measure. CMS retires or removes measures from Star Ratings when there is a change in clinical guidelines that mean that the measure specification is no longer believed to

align with or promote positive health outcomes and when measures show low statistical reliability. These standards are in §§ 422.164(e)(1) and 423.184(e)(1), and we explained how we interpret and apply the standards in the April 2018 final rule. When measure scores are “topped out” (that is, show high performance across all contracts), this decreases the variability across contracts and makes the measure unreliable. On average, measures improve year-to-year in the 1 to 3 percentage point range, with the exception of new measures where the performance generally has more substantial room for improvement or in situations where a structural change occurs (for example, implementation of EHR tools) that significantly alter performance on the measure.

Comment: A couple of commenters suggested convening a Technical Expert Panel (TEP) to provide input into the Tukey outlier deletion.

Response: A TEP comprised of representatives across various stakeholder groups convened on May 31, 2018 to provide feedback to the RAND Corporation, the current CMS contractor for the Part C and D Star Ratings program to obtain input on a number of issues, including increasing the stability of cut points (https://www.rand.org/pubs/conf_proceedings/CF391.html). This TEP focused on different ways to increase stability of cut points, including outlier deletion, but did not focus on the different methods for deleting outliers. We do not believe another TEP is necessary to specifically address this topic given the RAND TEP already expressed strong support for directly addressing outliers and this methodology for removing outliers is a widely accepted methodology for removing outliers.

Comment: A handful of commenters wanted to see the impact on their individual plans to be able to fully understand the effect of Tukey outlier deletion.

Response: CMS plans to display simulations of Tukey outlier deletion with mean resampling and guardrails for contracts to view in HPMS for the 2021, 2022, and 2023 Star Ratings prior to implementing the Tukey outlier change effective with the 2024 Star Ratings. These simulations will use the actual data that will be populating the 2021, 2022 and 2023 Star Ratings and will include all of the changes finalized related to cut point calculations. As noted in the NPRM, for the first year (2024 Star Ratings), we will rerun the prior year's thresholds, using mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. This, therefore, will be done for the simulations using the 2021 Star Ratings. This will provide information for multiple years for plans to see how the cumulative impact of the changes will impact the cut points going forward. Please note that currently mean resampling will be implemented with the 2022 Star Ratings, guardrails will be added with the 2023 Star Ratings, and Tukey outlier deletion will be implemented with the 2024 Star Ratings. Our planned simulations will illustrate the cumulative effect of all of these policies.

Comment: A commenter said CMS could further address outliers by removing contracts that are not eligible for Quality Bonus Payments such as 1876 cost plans and Medicare-Medicaid Plans.

Response: CMS does not include Medicare-Medicaid Plans in the calculation of cut points for the Part C and D Star Ratings since they currently do not receive Star Ratings on Medicare Plan Finder; however, although not eligible for bonuses, 1876 cost plans are part of the Part C and D Star Ratings program (see § 417.472(k)) and have historically received Star Ratings on Medicare Plan Finder so these contracts are included in the cut point calculations. Otherwise,

the ratings for public reporting would not be comparable for beneficiaries to use in evaluating their coverage choices.

Comment: A commenter asked for clarification about whether measures in the program for three or fewer years would be included in the Tukey outlier deletion.

Response: We are finalizing the proposed amendment to apply Tukey outlier deletion to all non-CAHPS measures, beginning with the 2024 Star Ratings. This application will be for all such measures regardless of the number of years the specific measure has been used in the Star Ratings program.

Comment: A number of commenters suggested publishing cut points in advance of the measurement year by relying on the data from earlier time periods, reinstating pre-determined 4-star thresholds, or designing cut points that establish clear national standards of care. Some of the commenters noted that announcing cut points prior to the measurement period would help plans and providers engage in value-based contracts that incentivize higher quality.

Response: CMS understands the interest in setting pre-determined cut points prior to the measurement year, but as stated previously in the April 2019 final rule (84 FR 15752-15754) there are numerous challenges in setting pre-determined cut points, including older data not being reflective of current performance, average performance not always increasing in a linear manner, external factors resulting in significant changes in performance from year to year, larger gains in performance generally seen for newer measures, and the rate of change differing for low performing contracts compared to higher performing ones. Additionally, the measures included in the Star Ratings program do not have national standards of care that plans or providers should meet; thus, it would be challenging to come to consensus on national standards to rate plans in the Star Ratings program. If using older data to predict or establish cut points, we risk causing

unintended consequences such as disincentivizing quality improvement or setting cut points that are not aligned to significant changes in industry performance. For example, no one could have predicted the significant impacts the COVID-19 pandemic would have on industry performance for various Star Ratings measures. The current methodology of hierarchical clustering using the current year's data will adjust cut points for the unforeseen impact on plan performance across the program. Since the clustering methodology compares relative performance, it protects plans from unanticipated impacts on industry performance. If there were pre-determined thresholds based on historical data or an independent standard, plans could end up all with uniformly low ratings when unanticipated situations such as the COVID-19 pandemic occur.

Comment: A number of commenters recommended including outliers in the cut point calculations since they represent the true performance of contracts on the measures. Commenters stated that without including these outliers, CMS would not fully be representing industry performance. Other commenters noted that with the current data integrity policies in place for the Star Ratings program, these outliers are legitimate measure-level contract scores.

Response: CMS agrees that an outlier may be a legitimate score for a particular contract, but we also know that extreme outliers for a measure in a given year can impact statistical analyses such as clustering. In the April 2019 final rule (84 FR 15755-15758) we received stakeholder feedback that in addition to guardrails and mean resampling we should directly address the impact of outliers. Although mean resampling does not directly address outliers, it helps mitigate the effect of outliers because when establishing the thresholds each data point (including outliers) is omitted from 10 percent of the cut points that are estimated (cut points are repeatedly estimated on ten subsets each containing 90 percent of the measure scores) and then averaged across the ten 90 percent samples following resampling. However, based on feedback

from the industry to further increase the stability of the cut points and to prevent large fluctuations in cut points from one year to the next caused by the scores of a few contracts, we proposed in the February 2020 proposed rule to more directly remove extreme outliers and are finalizing that policy.

Comment: A handful of commenters supported the addition of Tukey outlier deletion to the cut point methodology, while some suggested delaying implementation or viewing Tukey outlier deletion as an interim solution to improving the stability of the cut points. A commenter suggested phasing in outlier deletion over a multi-year period by putting the cut points with Tukey outlier deletion on display for two years.

Response: We appreciate the support for the addition of Tukey outlier deletion to the cut point methodology and have decided to delay the implementation for an additional year recognizing that there may be fluctuations in measure-level scores as a result of the COVID-19 pandemic. We will also display simulations for the 2021, 2022, and 2023 Star Ratings in HPMS for contracts to see the impact of removing outliers on their stars.

Summary of Regulatory Changes

After consideration of the comments and for the reasons indicated in the proposed rule and our responses to the related comments, we are finalizing as proposed the definition “Tukey outer fence outliers” and the specific formulae used. We are finalizing revisions to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the Tukey outlier deletion methodology prior to applying mean resampling with hierarchal clustering as proposed with one modification. To allow for potential fluctuations in measure-level scores as a result of the COVID-19 pandemic during the 2021 measurement year, we are delaying the addition of Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures until the 2022 measurement

year and the corresponding 2024 Star Ratings. Moving the effective date will provide an opportunity for MA and Part D contracts to view simulated results using Tukey outlier deletion for the 2021, 2022, and 2023 Star Ratings in HPMS. We note that the regulation text in this final rule incorporates the changes made by the IFC to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) during the period between the proposed rule and this final rule. The effect of Tukey outlier deletion would create a savings of \$935 million for 2025, increasing to \$1,449.2 million by 2030.

3. Removing Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted through rulemaking for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In the February 2020 proposed rule, CMS proposed the removal of the Rheumatoid Arthritis Management measure from the Star Ratings program for performance periods beginning on or after January 1, 2021.

CMS proposed to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. The measure steward, NCQA, is retiring this measure from the HEDIS measurement set for the 2021 measurement year due to multiple concerns. For example, there are concerns that the performance on the measure may not reflect the rate at which members get anti-rheumatic drug therapy because sometimes these medications are covered by Patient Assistance Programs, which do not generate claims. In terms of the measure construction, the measure assesses only if members received a disease-modifying anti-rheumatic drug once during the measurement year, rather than assessing if

members remain adherent to the medication. Additionally, it is unclear, based on the evidence, whether patients in remission should remain on these medications. Since NCQA plans to retire this measure from the HEDIS measurement set, CMS proposed to remove it starting with the 2023 Star Ratings.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Most commenters supported the retirement of the Rheumatoid Arthritis Management measure and offered a number of reasons for their support. Approximately half of the commenters who supported removal believed current measure specifications erroneously include certain patients in the measure denominator: those receiving medication through clinical trials, patient assistance programs, or other ways of paying; patients in remission or managing their illness with other drugs; and patients who have side effects or cannot tolerate disease-modifying anti-rheumatics drugs (DMARDS). A couple of commenters noted that the rate of medication adherence would be a better measure of patient outcomes than the current focus on DMARD dispensing. Individual commenters raised a number of additional issues with the measure: the role of the rheumatologist is not captured by the current measure; the measure has low reliability; there is no clinical consensus on whether patients in remission should remain on DMARD medications or should stop taking them at some point; removal of the measure will streamline ratings systems since NCQA has retired the measure from HEDIS; and continued use of the measure would promote unnecessary use of DMARDS.

Response: CMS will pass along to the measure developer suggestions made by commenters for additional research and new directions. NCQA has retired this measure and

therefore there will be no data for CMS to use in the Star Ratings program for the 2023 Star Ratings and beyond, so CMS will remove the measure from the Parts C and D Star Ratings.

Comment: A couple of commenters disagreed with CMS's proposal and offered similar explanations and recommended actions for CMS to take instead of removing the measure. The commenters note that there is room for improvement in the measure in some populations and in some regions. They also note that research is only beginning into the long-term outcomes of patients recovering without use of DMARDS. For these reasons, they suggest it is premature to update the specifications of the measure or to retire the measure. Instead, they suggest additional research into the long-term outcomes and functional status of patients recovering without use of DMARDS.

Response: CMS will pass along the suggestions for future research to the measure developer, NCQA. NCQA has retired this measure starting with the 2021 measurement year, so starting in 2021 this measure will no longer be submitted by plans and audited as part of the HEDIS measurement set. Thus, there will be no data for CMS to use in the Star Ratings program for the 2023 Star Ratings and beyond. Additionally, CMS agrees with NCQA's assessment of the need to retire this measure at this time.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the removal of the Rheumatoid Arthritis Management measure.

4. Measure Weights (§§ 422.166(e), 423.186(e))

As finalized in the April 2018 final rule, beginning with the 2021 Star Ratings, §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv) provide that the weight for patient

experience/complaints measures and access measures will increase to 2. We stated in the April 2018 final rule (83 FR 16575-16576) that given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intends to further increase the weight of patient experience/complaints measures and access measures in the future. The measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. We stated the majority of the measures impacted by the proposed weight change are the CAHPS measures that focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best or only source of information.

We explained the proposed increase in the weight would not impact the assignment of stars at the measure level, just the calculation of the overall and summary ratings, and would not impact the distribution of stars which varies for each of these measures. The statistical reliability of the CAHPS measures is high, exceeding standards for quality measurement so that higher star categories correspond to meaningfully better performance (generally, reliabilities of 0.7 or more are considered high for a quality measure²²). The inter-unit reliability of the CAHPS measures range from 0.7638 for Customer Service to 0.9215 for Rating of Health Plan measure. The reliability for the other measures is as follows: Care Coordination is 0.8155, Getting Appointments and Care Quickly is 0.9059, Getting Needed Care is 0.8543, Getting Needed Prescription Drugs is 0.7895, Rating of Drug Plan is 0.8937, and Rating of Health Care Quality is 0.8263.

²² https://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR653.pdf

CMS has pledged to put patients first and to empower patients to work with their providers to make health care decisions that are best for them. To best meet the needs of beneficiaries, CMS believes we must listen to their perceptions of care, as well as ensure that they have access to needed care. Thus, CMS proposed to modify §§ 422.166(e) and 423.186(e) at paragraphs (e)(1)(iii) and (iv) to increase the weight of patient experience/complaints measures and access measures to 4 to further emphasize the importance of patient experience/complaints and access issues

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters opposed the weight increase of patient experience/complaints and access measures from 2 to 4. Most of these commenters argued that CMS should not value patient experience over clinical outcomes (currently weighted as 3) as they believe clinical outcome measures are the most important. Because some plans may not have enough enrollees to report all of the outcome measures included in the Star Ratings program, some commenters argue the proposed weighting changes would create an even greater imbalance between the total weight given to patient experience measures versus clinical outcome measures for these plans. A commenter stated that since the intended purpose of the Star Ratings program is to compare plan performance on measures related to beneficiary health outcomes and experience, the increase has the potential to erode the integrity of the Star Ratings program by basing the majority of the Star Rating score on patient experience and complaints measures instead of clinical outcomes.

Response: CMS appreciates the value commenters place on outcome measures and will continue to advance work in the area of developing new outcome measures. That being said, it is important to make sure the voice of patients is heard and that patient experience is a key

component of the overall and summary Star Ratings. Part of putting patients first and promoting patient-centered care is focusing on patients' perspectives. Additionally, for those plans that may not have enough enrollees to report all of the outcome measures included in the Star Ratings program, we believe that this increased weighting of experience measures would provide such plans an opportunity to focus on improving patient experience and differentiate themselves in the market as a plan that anticipates members' needs and works with enrollees in a customized way. Consequently, we are emphasizing CMS's goal of listening to the voice of the patient to identify opportunities to improve care delivery. Under 1851(d) of the Act, CMS must provide information to promote an active, informed selection among plans, and hearing the perspective of beneficiaries is critical to understanding the differences among options. Weighting these measures higher will accomplish this goal.

Comment: A number of commenters argued that by increasing the patient experience/complaints measures and access measures from a weight of 2 to 4, CMS will be downplaying the importance of the provision of high quality clinical care. Some commenters also noted that this would not align with other CMS quality measurement programs, such as the Health Insurance Exchanges Quality Rating System (QRS), the underlying goals of the Part C and D Star Ratings program and non-Medicare quality improvement efforts, or with CMS's guiding principles for the Star Ratings program. A commenter noted that this contradicts the U.S. Department of Health and Human Services' (HHS') efforts as part of the Quality Summit to align federal healthcare quality rating programs. A commenter noted that the proposal also runs counter to the quality measurement principles of MedPAC, which establish the importance of outcome measures.

Response: The proposed increase in weight for patient experience/complaints measures and access measures is a new direction for the Part C and D Star Ratings program to advance the agency's goal of putting patients first and listening to their voice. While this direction differs from current policies in other quality programs, it is part of the agency's effort to strive to ensure we are meeting the needs of our beneficiaries by listening to their feedback through the CAHPS survey measures, disenrollment rates, and complaints measures. A primary function of Medicare health and drug plans is the provision of health care and drug services to beneficiaries. Measuring, and highly weighting, the importance of access to these services greatly encourage the industry to focus on their fundamental functions. Without access to care and needed prescription medications, optimal clinical outcomes are not probable. CMS believes access to services, care coordination, and patient engagement are intrinsic to positive clinical outcomes. A beneficiary's confidence in the health and drug plan helps facilitate continuation of care which could lead to better clinical outcomes. We agree with MedPAC's recommendation that population-based outcome and patient experience measures are critical in evaluating MA quality.

Comment: Commenters also raised concerns that this would take focus away from physician care and the clinical measures collected through HEDIS. Other commenters noted that the overwhelming emphasis on patient experience could have the unintended consequence of MA plans and providers not focusing on preventive screenings, such as colorectal cancer screening, which can save lives.

Response: Plans and providers should continue to focus on preventive care, screenings, and physician care. This weight change puts more emphasis on the voice of the beneficiary and access issues. We disagree with the characterization that this emphasis is overwhelming, and it in no way suggests that plans and providers should not be continuing to provide important

preventive care and screenings. All MA and Part D sponsors are still required to have quality improvement (QI) programs described at §§ 422.152 and 423.153(c), respectively, in place. The primary goal of the MA organization's QI program is to effect sustained improvement in patient health outcomes. Additionally, by not continuing to focus on preventive screenings and primary care, this will have a detrimental effect on health outcomes and would have an impact on patient experience measure scores, disenrollment rates, and complaint rates, all measures included in the weight increase. Therefore, the risk of this particular negative outcome from the change in weighting the patient experience/complaints measures and access measures is minimized.

Comment: A number of commenters expressed concerns about what they perceive to be a fundamental, unprecedented shift away from the objective data-driven clinical Star Ratings measures to more subjective patient experience measures and encouraged a more thoughtful approach to ensure that the weight increase would not result in unintended consequences. Commenters raised issues regarding CMS creating incentives for plans and providers to provide care that would lead to increased CAHPS scores, and they argued this may not be in the best interest of Medicare beneficiaries and better health outcomes.

Response: Plans and providers should always be providing professional, appropriate clinical care to Medicare beneficiaries, thereby focusing broadly on quality, rather than on narrowly targeted metrics represented by individual Star Ratings measures. Patient experience is a fundamentally important aspect of healthcare quality. Most of the evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer inpatient complications (Anhang Price et al., 2014;

Anhang Price et al., 2015²³). The Anhang Price et al., 2014 article which consisted of a review of relevant literature related to CAHPS surveys and their relationship to health care quality found that all but one out of almost three dozen studies reviewed showed a positive correlation between patient experiences and clinical care quality or were neutral. The empirical evidence in the studies highlights that health care providers and plans can concurrently provide better patient experiences and better clinical quality. As discussed in the article, patient experience of care surveys such as the CAHPS surveys evaluate a critical component of care and focus on whether the care is patient-centered. This is an important goal as we continue to emphasize the importance of putting patients first.

Comment: A few commenters expressed concerns that this change would encourage plans to abandon efforts to drive clinically appropriate care in lieu of catering to popular opinion that may be biased by advertisements and media. Such behavior, it was noted, could result in degraded health outcomes long-term for Medicare beneficiaries. They argue programs that promote member health and safety, such as drug management and utilization programs, could be damaged or abandoned. A number of commenters stated that the improvement of health outcomes is one of the largest drivers of the long-term goal of reducing American health care costs and that shifting emphasis from clinical outcomes to member experience could lead to increased medical and pharmaceutical spending.

Response: Plans and providers should continue to focus on improving health outcomes, while also ensuring that Medicare beneficiaries have access to clinically appropriate and needed

²³ Anhang Price, R., Elliott, M. N., Zaslavsky, A. M., Hays, R. D., Lehrman, W. G., Rybowski, L., Edgman-Levitan, S. & Cleary, P. D. (2014). Examining the role of patient experience surveys in measuring health care quality. *Medical Care Research and Review*, 71(5), 522-554.
Anhang Price, R., Elliott, M. N., Cleary, P. D., Zaslavsky, A. M., & Hays, R. D. (2015). Should health care providers be accountable for patients' care experiences?. *Journal of general internal medicine*, 30(2), 253–256. <https://doi.org/10.1007/s11606-014-3111-7>

care, for example as measured through the CAHPS surveys, Appeals, Members Choosing to Leave the Plan, and Complaints measures. Outcome measures are still heavily weighted in the Star Ratings program with a weight of 3. We believe high quality care is meaningless unless the enrollee has access to that care. All MA and Part D sponsors are required to have quality improvement (QI) programs described at §§ 422.152 and 423.153(c), respectively, in place. The primary goal of the MA organization's QI program is to effect sustained improvement in patient health outcomes and providing health care using evidence-based clinical protocols. The QI program must also include a health information system to collect, analyze, and report Medicare Parts C and D quality performance data, including HEDIS, HOS, and CAHPS data. Additionally, as described at § 422.152(c), an MA organization's QI program must include a chronic care improvement program. Part D sponsors must also have established quality assurance measures and systems in place to reduce medication errors and adverse drug interactions and improve medication use. In addition to the requirements to focus on clinical-based care, MA and Part D plans, given their payment structures should have incentives to decrease inappropriate medical and pharmaceutical spending.

Comment: Some commenters argued that if physicians do not proceed thoughtfully, patient experience measures could easily result in adverse consequences that are potentially dangerous to the patient. A commenter noted that if a person who is addicted to opioids seeks a prescription and the physician does not provide one, the patient could retaliate by leaving a negative review. It was suggested that in some cases physicians who overprescribe opioids may have very high reviews from patients, despite putting patients in real danger and contributing to the nation's opioid epidemic.

Response: The CAHPS survey questions are based on statistically valid samples of Medicare enrollees in each contract and should not be influenced by a particular physician providing opioids or not. They are not like crowd-sourced reviews. Most of the CAHPS survey questions focus on enrollees' experiences of care such as whether they got an appointment to see a specialist as soon as they needed, whether they got care as soon as they needed, whether the health plan's customer service gave them the information or help needed, and whether the doctor's office followed up on test results²⁴. There are also global ratings of the health care quality, health plan, and drug plan. The change in measure weights does not suggest that any physicians behave in a manner that puts patients in danger, nor does it provide an excuse for a physician who does so.

Comment: A few commenters supported the increased weight of patient experience/complaints measures and access measures but only if the increase is gradual by moving it to a weight of 2.5 or 3 first to promote stabilization of the Star Ratings. It was noted that this proposal is a radical increase considering that CMS had maintained for eight consecutive Star Ratings cycles (2012-2019) the original weight of these measures (at a weight of 1.5). Commenters argued that when changes are made to an organization's culture, it can take years to see the improvements in patient experience scores since many beneficiaries interact with the health care system only a few times a year.

Response: We disagree that this is an unexpected and sudden change. The April 2018 final rule adopted an increase from 1.5 to 2 in the weight of patient experience and complaints measures and access measures. CMS signaled in that final rule that, given the importance of

²⁴ CAHPS composite items included in the Part C & D Star Ratings are: Getting Needed Care, Getting Appointments and Care Quickly, Customer Service, Care Coordination, and Getting Needed Prescription Drugs. All of these measures are considered patient experience of care measures.

hearing the voice of patients when evaluating the quality of care provided, we intended to further increase the weight of these measures in the future. While we appreciate that organizations are being incentivized to quickly adjust to this weighting change, we believe it is important to proceed at this time, in particular, in light of the COVID-19 pandemic. The uncertainty from the pandemic is a critical time for plans to be focused on patient experience. Plans need to enhance patient experience to deal with the challenges of COVID-19 pandemic, to work with beneficiaries in customized ways, and be as supportive as possible. This is also an opportunity for them to distinguish themselves and be innovative in maintaining access to care. A goal of the Star Ratings program is to foster continuous improvement.

Comment: A handful of commenters opposed the weight increase for measures from the CAHPS survey. These commenters argued that the CAHPS survey measurement tool and methodology are outdated and need to be updated to accurately capture beneficiaries' perspectives of care since the private insurance market has significantly changed over time. Some commenters opposed the survey due to a variety of other reasons, including what they perceive as a lack of statistical reliability, small sample sizes, compression of cut points, differences in methodologies across CAHPS surveys and with the NCQA rating system, cut point variability, contract-level rating volatility, and lack of clinical relevance. A commenter stated that the measures are based on a limited sample that may yield inaccurate, unreliable, or biased data. A commenter stated that younger patients, those with disabilities, and members enrolled in a D-SNP are underrepresented in the survey. A couple of commenters stated that the CAHPS survey has no mechanism for health plans to identify and address negative experiences for a particular enrollee; therefore, these commenters encouraged CMS to release secure

beneficiary-level CAHPS response data. A commenter said survey data should receive third-party validation.

Response: CAHPS measures focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best or only source of information. As a result of more than twenty years of research that is ongoing and leading to continuous improvement, CAHPS surveys are very good measures of patient experience. The CAHPS program, initiated in 1995, which includes the Medicare CAHPS Health Plan Surveys, seeks to advance the scientific understanding of patient experience with healthcare. Since then, CAHPS surveys have become recognized as the most widely validated, reliable, and applied patient experience surveys in the United States (Holt et al. 2019). Many articles documenting the reliability and face, content, and construct validity of the CAHPS surveys have been published (for example, Crofton, Lubalin, & Darby, 1999; Darby, Hays, & Kletke, 2005; Hays et al., 2014; Martino et al., 2009). In addition, many studies establish the validity of CAHPS measures by assessing their association with measures of structures, processes, and outcomes. For example, the 2014 review article (Anhang Price et al., 2014), in reviewing 34 studies, found that evidence indicated positive associations between patient experiences and other aspects or indicators of health care quality, including patient behavior (adherence), best practice clinical processes, better patient safety culture, and lower unnecessary utilization²⁵.

²⁵ Anhang Price, R., Elliott, M. N., Zaslavsky, A. M., Hays, R. D., Lehrman, W. G., Rybowski, L., Edgman-Levitan, S. & Cleary, P. D. (2014). Examining the role of patient experience surveys in measuring health care quality. *Medical Care Research and Review*, 71(5), 522-554.
Crofton, C., Lubalin, J. S., & Darby, C. (1999). Consumer Assessment of Health Plans Study (CAHPS). Foreword [Review]. *Medical Care*, 37(3 Suppl.), MS1-MS9.

The Medicare CAHPS survey is designed to capture changes in the insurance market that may adversely affect patient experience. The survey measures patient experience with care and captures whether enrollees in MA plans with narrow networks or closed panels or providers who are not accepting new patients have less positive experiences or receive lower quality care in the responses to existing questions on the survey. If care is worse in some MA contracts because of these aspects of how care is provided, the survey functions as intended by identifying and reporting these differences to beneficiaries, contracts, and CMS.

The statistical reliability of the CAHPS measures is high, so that higher star categories correspond to meaningfully better performance. Generally, reliabilities of 0.7 or more are considered high for a quality measure (Price, Elliott, Zaslavsky, et al., 2014). The reliability of Medicare CAHPS measures ranges from 0.76 to 0.92. Contracts may further increase the reliability of their own scores by requesting sample sizes greater than the required minimum.

While the star category bands may appear to be narrow, the reliability of CAHPS measures meet or exceed standards for quality measurement (Adams 2009²⁶), so that higher star categories correspond to meaningfully better performance. While the CAHPS scoring using linear means may make between-plan differences appear to be compressed, the high contract-level reliability establishes excellent ability to differentiate plan performance. Based on the peer-reviewed measurement and quality-measurement literature, experts in measurement generally

Darby, C., Hays, R. D., & Kletke, P. (2005). Development and evaluation of the CAHPS hospital survey. *Health Services Research*, 40(6 Pt 2), 1973-1976.

Hays, R. D., Martino, S., Brown, J. A., Cui, M., Cleary, P., Gaillet, S., & Elliott, M. (2014). Evaluation of a care coordination measure for the Consumer Assessment of Healthcare

Providers and Systems (CAHPS) Medicare survey. *Medical Care Research and Review*, 71, 192-202.

Holt, J. M. (2019). Patient experience in primary care: a systematic review of CG-CAHPS surveys. *Journal of Patient Experience*, 6(2), 93-102.

Martino, S. C., Elliott, M. N., Cleary, P. D., Kanouse, D. E., Brown, J. A., Spritzer, K. L., Hays, R. D. (2009). Psychometric properties of an instrument to assess Medicare beneficiaries' prescription drug plan experiences. *Health Care Financing Review*, 30(3), 41-53.

²⁶ https://www.rand.org/pubs/technical_reports/TR653.html

agree that reliability greater than 0.70 indicates acceptable reliability; reliabilities of 0.80 or greater are preferable for higher-stakes applications (Adams et al. 2010, Elliott et al. 2010; Nunnally & Bernstein, 1994; Roland et al. 2009; Safran et al., 2006)²⁷.

The differences between CMS's Medicare CAHPS implementation and others largely reflect CMS's use of additional survey items, case-mix adjustment, and reliability and statistical significance criteria to improve the validity, reliability, and accuracy of Medicare CAHPS scores and stars (<https://www.ma-pdpcahps.org/globalassets/ma-pdp/scoring-and-star-ratings/2019-analysis-of-reported-measures.pdf>); several of these beneficial features are not included in other CAHPS implementations. For example, the CMS Medicare CAHPS Getting Appointments and Care Quickly composite includes a highly-reliable item that is not present in alternate versions. The use of percentile cutoffs, combined with reliability and statistical significance testing, reduces the effects of chance and results in reliable, valid star assignment for CAHPS measures. This methodology, combined with highly-reliable underlying scores, ensures that changes in cut points reflect changes in contract performance rather than chance. These changes in cut points ensure that CAHPS Star Ratings continue to accurately differentiate contract performance.

Patient experience is an inherently important dimension of healthcare quality. It is also the case that the preponderance of evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital

²⁷ Adams, J. L., Mehrotra, A., Thomas, J. W., & McGlynn, E. A. (2010). Physician cost profiling—reliability and risk of misclassification. *New England Journal of Medicine*, 362(11), 1014-1021.

Elliott, M. N., Lehrman, W. G., Goldstein, E., Hambarsoomian, K., Beckett, M. K., & Giordano, L. A. (2010). Do hospitals rank differently on HCAHPS for different patient subgroups? *Medical Care Research and Review*, 67(1), 56-73.

Nunnally, J. C., & Bernstein, I. H. (1994). *Psychometric theory* (3rd ed.). New York: McGraw-Hill.

Roland, M., Elliott, M., Lyratzopoulos, G., Barbiere, J., Parker, R. A., Smith, P., ... & Campbell, J. (2009). Reliability of patient responses in pay for performance schemes: analysis of national General Practitioner Patient Survey data in England. *British Medical Journal*, 339, b3851.

Safran, D. G., Karp, M., Coltin, K., Chang, H., Li, A., Ogren, J., et al. (2006). Measuring patients' experiences with individual primary care physicians: Results of a statewide demonstration project. *Journal of General Internal Medicine*, 21, 13-21.

patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015).

Medicare CAHPS case-mix adjustment, which is informed by 20 years of research, accounts for factors such as age, health status, and dual eligibility and ensures that contract scores are not influenced by patient-level factors beyond their control. This adjustment ensures that contract-level scores fairly represent all contracts. Analyses of nonresponse in CAHPS data (Elliott et al. 2005; Elliott et al. 2009) have shown little or no evidence of nonresponse bias in the presence of CAHPS case-mix adjustment.

Medicare CAHPS survey vendors have access to beneficiary-level data and are permitted to conduct analyses with these data that do not risk disclosing the identity of respondents to plan sponsors, including restrictions on reporting cell sizes smaller than 11. These restrictions are necessary to ensure the confidentiality and validity of beneficiary responses to the Medicare CAHPS survey.

The collection and processing of CAHPS data undergo a rigorous quality assurance process that includes dual program coding, use of test data sets, team review of products, investigation of outliers, and comparisons to historic results. This quality assurance process is as rigorous as that followed for the production of other quality measures.

Comment: A couple of commenters suggested different updates to the content of the CAHPS survey. A commenter recommended that the Agency for Healthcare Research and Quality (AHRQ) and CMS consider expanding the survey to include questions on accuracy of provider directories and ease of accessing the information. Another commenter noted that questions on the CAHPS survey are not consistent across different lines of business.

Response: The Medicare CAHPS Survey was updated in 2016 to incorporate AHRQ's 5.0 updates to the CAHPS Health Plan Survey. CMS uses the most current version of the CAHPS Health Plan Survey as it is the national standard for measuring and reporting on the experiences of consumers with their health plan, and the only assessment of patient experiences with health plans endorsed by the National Quality Forum. In May 2019, AHRQ published a request for information inviting public comment to inform potential revisions to the Health Plan Survey (84 FR 21340). CMS will give careful consideration to any updates to the CAHPS Health Plan Survey that AHRQ may provide in the future. Additional testing and development to refine CAHPS items in areas such as care coordination is ongoing. With regard to adding questions around provider directories and ease of accessing plan information, specific measures of information seeking, such as experience with written health plan materials, have been explored in the context of CAHPS but have not resulted in reliable measures due to too few plan members reporting experience in the survey samples. CMS is exploring alternate ways of improving the accuracy of plan directories. Differences in CAHPS composite items across lines of business, such as in the Getting Appointments and Care Quickly composite, in some cases reflect additional items that Medicare CAHPS includes to maximize the reliability and validity of the CAHPS measures.

Comment: A commenter supported the increase in the weight for administrative access measures but suggested keeping the CAHPS measures at their current weight because the administrative measures already take into account member experience. Another commenter said they would support an increase in access measures because plans have a direct impact on the outcome of these measures and can analyze, pinpoint root causes, and take action to avoid adverse outcomes.

Response: We appreciate these comments. CMS wants to ensure that the experiences of beneficiaries getting needed care, getting appointments and care quickly, care coordination, and ratings of health care quality, for example, are also emphasized with this weight change. MA plans are responsible for providing all of the Part A and B benefits and providing a managed care alternative to the traditional FFS Medicare program. In some cases, the MA plans provide additional (supplemental) benefits. One of the advantages of MA is the MA plan is responsible for coordinating the care among the enrollee's health care providers. Since the primary purpose of the health plan is to ensure their enrollees get needed health care services, patient experience and access measures that focus on whether the enrollee is getting needed care are critical in evaluating whether a plan is fulfilling its fundamental requirements.

Comment: A couple of commenters opposed the weight increase for access measures but also asked for clarification and requested a methodology change to the Call Center measures. A commenter requested CMS consider publishing Call Center results in HPMS on the same frequency as the Part C and Part D Timeliness Study (quarterly) to allow plan sponsors to better align internal testing/monitoring against CMS third-party testing. A commenter asked for clarification on the definition of the "Call Center," noting it is unclear if this encompasses the Star Ratings measure for prospective members or if this is in reference to the member customer service call center.

Response: While we appreciate feedback on the usefulness of the Accuracy and Accessibility Study results and the request for publication of those results quarterly, we cannot do this because of the timing of the study. The Timeliness Study is conducted quarterly, and CMS publishes the results quarterly; conversely the Accuracy and Accessibility Study is conducted once a year, between February and May, and CMS publishes the results once a year,

as soon as they are available in August. For purposes of the Star Ratings measure, the prospective customer service call center results are included in the measure calculation. The measure specification has not changed from prior years.

Comment: A few commenters opposed the current appeals measures and, consequently, did not believe the higher weight was prudent. One noted that these measures are distorted because beneficiaries may be unaware of the extent to which they are or are not receiving the proper benefits. The commenter recommended CMS conduct a survey of providers on how efficiently and accurately MA plans make organizational determinations and appeals. A commenter expressed concern regarding increasing the weight for appeals measures citing what they believe are fundamental flaws in these measures. They stated both the plan and Independent Review Entity (IRE) have difficulty reaching sound decisions in the 72 hour timeframe and argued the IRE demonstrates the same lack of medical expertise or misunderstanding of coverage guidelines as the MA plan; the commenter recommended providing more meaningful measures such as independent audits of the MA plans' initial determinations, the frequency with which physicians appeal MA plans initial determinations, the timeliness of initial determinations (using a much shorter standard than 72 hours), and other measures they say capture the patient and provider experience more accurately. A commenter stated health plans should be held accountable for their administrative responsibilities and insurance functions through compliance standards and plan monitoring, not Star Ratings.

Response: CMS clarifies that both Part C appeals measures assess the timeliness of appeals sent to the IRE and how often the IRE agrees with the plan's decisions. The purpose of these measures is not to directly assess the enrollees' comprehension of all of their plan benefits. CMS acknowledges the comments for new measurement suggestions for the Part C appeals

process and is actively evaluating these suggestions for future measure development. However, CMS does not agree that there are fundamental flaws in the current Part C Appeals measures. The purpose of the appeals measures is to ensure appeals that are denied are processed in a timely manner and to assess if the denial by the health plan was consistent with the benefit or coverage requirements. CMS reminds plans that they can access timeliness and compliance data in real time at www.medicareappeal.com and bring to the attention of the IRE any data discrepancies. CMS disagrees that both the plan and IRE have difficulty making sound decisions in the 72-hour time frame and both lack the medical expertise or misunderstand the coverage guidelines. CMS notes only expedited reconsiderations must be sent to the IRE within 72 hours for Part C appeals (see § 422.590). In these cases this timeframe is required to avoid endangering the life or health of the enrollee or the enrollee's ability to regain or maintain maximum function; thus, a de novo review of an adverse organization determination must be processed quickly. Examples of cases that should be expedited include pre-service skilled nursing facility cases, pre-service acute inpatient care cases and cases in which a physician indicates that applying the standard timeframe for making a determination could seriously affect the life or health of the enrollee or the enrollee's ability to regain maximum function. Medicare health plans have an obligation to determine if an appeal should be expedited, including responding to an enrollee or provider request for expedited determination. We also remind plans that in expedited and standard service appeals, IRE may extend the decision timeframe by up to 14 calendar days if it is in the enrollee's interest.

Please remember if a plan fails to provide the appellant with a reconsidered determination within the required timeframes, this failure constitutes an affirmation of its adverse organization determination, and the plan must submit the case file to the IRE for review. Plans and sponsors

must continue to have procedures in place for requesting and obtaining information necessary for making timely and appropriate decisions. The IRE's decision is based on the information gathered during its review process and the IRE must issue a decision within the same appeals timeframe as the plan. Please refer to 42 CFR 426.600(d). Therefore, the timeframes for the plan and the IRE are aligned.

In response to the recommendation that plans be held accountable for their administrative responsibilities and insurance functions through compliance standards and plan monitoring instead of Star Ratings, we assure commenters that this also happens. The Star Ratings measures only focus on two aspects of the appeals processes. Program audits provide a more comprehensive review of a sponsoring organization's compliance with the terms of its contract with CMS, including access to medical services and other enrollee protections required by Medicare. For more information about the program audit process, please see <https://www.cms.gov/files/document/2020-program-audit-process-overview.pdf>. The purpose of the Star Ratings system is to measure quality of a health and drug plan and to provide information to help beneficiaries make more informed choices. The appeals measures are such indices of quality.

Comment: A few commenters focused their comments on the Complaints about the Health and Drug Plan measures. A commenter said they support a modest increase in weight for these measures because plans are generally able to analyze the root cause of the complaint and implement strategies to address beneficiary concerns. A few commenters noted that complaints not within the plans' control and complaints resulting from CMS policy decisions should be excluded.

Response: CMS thanks the commenter for their support of a modest increase in the weight of the complaints measure. Although a few commenters noted that complaints not within the plans' control and complaints resulting from CMS policy decisions should be excluded, CMS expects plans to be integral in assisting beneficiaries and ensuring their access to care is not disrupted, regardless if they directly created the issue at question, or not. CMS expects health plans and Part D sponsors will assist their enrollees in situations such as these, and help them understand how to correct issues, even if the underlying cause of complaints is not the sponsors' fault. Sponsors have an important responsibility for providing continued access to services. The fact that CMS received a complaint indicates the sponsor has not helped service their enrollee, as Medicare instructs beneficiaries to seek resolution first through their sponsors. If sponsors take the opportunity to assist their enrollees proactively, they will avoid having complaints recorded in the Complaints Tracking Module (CTM). CMS issued guidance in the HPMS memo dated May 10, 2019, Complaints Tracking Module (CTM) File Layout and Updated Standard Operating Procedures, which describes the Plan Request process for plans to submit requests to change incorrect contract assignments, change issue designation (that is, from Plan Issue level to CMS Issue), and change category/subcategory. The memo states that, for matters that are delegated to CMS for handling and/or final resolution, plans are to submit a CMS Issue Change Request and it lists examples of applicable situations. In the SOP Appendix A, CMS lists the subcategories and notes which subcategories are excluded from plan performance metrics.

Comment: A few commenters focused their comments on the disenrollment measure, Members Choosing to Leave the Plan, stating that the measure is flawed and misrepresents some changes in enrollment as dissatisfaction. They suggest CMS consider excluding members who switch plans but stay with the same parent organization, as it may actually suggest a high level of

satisfaction with the parent organization. A commenter stated the measure is extremely volatile and can be impacted by many factors beyond a member's experience with their health plan, including job loss /movement, changes in individual finances, provider changing plans, relocations and changes in member needs.

Response: CMS appreciates these comments, but disagrees that the current specification for this measure is flawed. This measure reflects voluntary movements from one contract to another. For example, if a change in the provider network results in a beneficiary changing contracts, this reflects a decision by the beneficiary that the current contract is no longer providing the care or access to services that they want. Similarly, if the health status of the enrollee changes, and the current plan is not meeting the enrollee's changing health needs, this may result in a voluntary disenrollment and should be reflected in this measure.

This measure is a contract-level measure focused on quality at that level; therefore, disenrollments are considered voluntary even when a member enrolls into a different contract under the same parent organization. The member is changing from one contract to another for a reason and this should be reflected in this measure. If we were to change the measure specification to consider disenrollments as no longer voluntary when a member enrolls into another contract under the same parent organization, this change would be advantageous to larger parent organizations that have multiple contracts.

There are only 4 disenrollment codes used in this measure (11 - Voluntary Disenrollment through plan, 13 - Disenrollment because of enrollment in another Plan, 14 – Retroactive and 99 - Other (not supplied by beneficiary)). We agree that there are reasons for disenrollment that should not be counted against the plan. For example, enrollment changes because of a contract service area reduction, a PBP termination, LIS reassignments, passive enrollment of the enrollee

into a Demonstration (MMP), and changes in residence out of the service area are not counted in the measure.

Comment: Some commenters supported the weight increase, indicating they appreciate CMS adding further emphasis on the voice of the patient. Some argued that better patient experience has been shown to improve patient compliance with medical advice.

Response: CMS appreciates the commenters' support of our proposal.

Comment: Several commenters expressed concern about implementing a weighting change during the COVID-19 pandemic because of the current uncertainty how the public health emergency will impact care delivery and patient experiences going forward. One noted this weight change would not give health plans adequate time to adjust for the volatility and inconsistency of CAHPS responses and difficulties in measurement during this time. A couple of commenters noted that depending on the state of the pandemic, additional weight afforded to the current patient experience and complaints measures will not accurately capture plan performance during this public health emergency and crisis. Another commenter noted patient experience data during this period may not be particularly accurate or useful as a measure of overall performance of Medicare Advantage or individual plans due to how the pandemic may impact how beneficiaries may respond to these types of surveys.

Response: The changes to the weighting of patient experience/complaints and access measures apply to the 2021 measurement year, not the 2020 measurement year when the pandemic first started. CMS agrees that there is a lot of uncertainty about how COVID-19 will impact the healthcare system and quality measurement and recognizes the challenges placed on the healthcare system and Part C and D plans; however, plans have until the 2021 measurement year to adjust their processes to account for the impact of COVID-19 on Star Ratings measures.

One thing that is certain for plans is how much they focus on addressing their members' needs during the time of a pandemic. We believe that given the uncertainty during such times, it is even more important that plans be proactive, anticipate enrollees' needs, and work with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment. Therefore, it is important to move forward with these Star Ratings changes to further emphasize the importance of patient experience/complaints and access measures at this time. We reiterate that patient experience is an inherently important dimension of healthcare quality and associated with better health outcomes and improved care delivery. This is critical information to help beneficiaries make more informed choices.

Comment: Some commenters noted that different areas of the country are experiencing different limitations of health care resources related to COVID-19, some of which may require redeployment of resources, so differences in CAHPS and HOS survey scores may be neither meaningful nor appropriate to compare plan performance. They request that CMS re-evaluate these measures after the COVID-19 crisis is resolved. Several commenters noted their concern about the long-term impact of the public health crisis on respondents' physical and mental health, and their perception of the health care system and health plans.

Response: CMS recognizes the challenges that COVID-19 has placed on the healthcare system and quality measurement. We understand the concern that it may impact how beneficiaries respond to CAHPS surveys and, consequently, the CAHPS measure scores. To that end, we believe that this would be a great opportunity for plans to focus even more on supporting their enrollees, being proactive and anticipating enrollees' needs, and working with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment.

We are continuing to monitor whether additional Star Ratings adjustments need to be proposed for future years.

Comment: Several commenters stated the weight increase should not proceed at this time due to widespread restricted access to providers due to concern about capacity and public safety as a result of COVID-19, and the unknown duration of such restrictions. For example, beneficiaries may not be able to assess their experience with in-person encounters, and responses may be biased by exigencies secondary to COVID-19. One notes the proposed CAHPS weight changes for the 2021 measurement period provide little time for health plans to adjust for the volatility and consistency of CAHPS responses and difficulties in measurement.

Response: Again, we believe that this would be the ideal time for plans to take the opportunity to focus even more on supporting their enrollees, being proactive and anticipating enrollees' needs, and working with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment, particularly challenges in accessing services. As previously stated, these changes are for the 2021 measurement period so plans have time to adjust to the impacts of COVID-19. Even in a pandemic environment, increasing the weight for experience measures will encourage plans to focus on an enrollee's experience with the plan (for example, plan communication, plan innovation, mitigation of access issues). CMS will continue to monitor the impact of the public health emergency on quality measurement. For CAHPS measures, widespread changes in industry performance should be reflected in the cut points.

Summary of Regulatory Changes

After consideration of the comments and for the reasons indicated in the proposed rule and in the responses to comments, we are finalizing the provisions regarding the weight increase

for patient experience/complaints and access measures as proposed at §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv).

In the proposed rule, we stated that if both Tukey outlier deletion and increasing the weight of patient experience/complaints measures and access measures were adopted the net savings for the Medicare Trust Fund would be \$368.1 million for 2024, increasing to \$999.4 million for 2030. We are finalizing the use of Tukey outer fence outlier deletion as proposed but to begin one year later, with the 2024 Star Ratings, and are finalizing the proposal to increase the weights of the patient experience and complaints measures and the access measures to 4 for the 2023 Star Ratings. Based on the combination of these final policies, we project the net cost to the Medicare Trust Fund would be \$345.1 million for 2024, increasing to a net savings of \$999.4 million for 2030. There is a net cost for 2024 since the increase in weight for patient experience/complaints measures and access measures results in an overall increase in the highest ratings for MA contracts, while in future years with the addition of the Tukey outlier deletion there is an overall decrease in the highest ratings for MA contracts.

5. Reclassification of the Statin Use in Patients with Diabetes (SUPD) measure (§§ 422.164(d)(2), 423.184(d)(2)).

Currently, the SUPD measure specifications require two diabetes medication fills to meet the denominator while only a single fill of a statin therapy is required to meet the numerator criteria. Recently, the Pharmacy Quality Alliance (PQA), the measure steward, has clarified SUPD as a process measure in a Frequently Asked Question (FAQ) (the FAQ can be found at <https://www.pqaalliance.org/measures-overview#supd>), therefore CMS no longer believes that the intermediate outcome measure classification for the SUPD measure is appropriate. We proposed to modify the classification of the SUPD measure from an intermediate outcome

measure to a process measure, starting with the 2023 Star Ratings, based on data from the 2021 measurement period.

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters supported modifying the SUPD measure classification from an intermediate outcome to a process measure, changing the weight from 3 to 1. Commenters noted that outcomes are not measured in SUPD since it only requires a single fill of a statin medication. They agreed that SUPD is a process measure that is based on an important procedural intervention but does not capture a therapeutic outcome since SUPD does not monitor the medication adherence of a statin over a course of treatment. In addition, commenters noted that classifying SUPD as a process measure is consistent and aligns with the Part C Statin Therapy for Patients with Cardiovascular Disease measure.

Response: CMS appreciates the commenters' support of this proposal. It is consistent with the clarification from the measure steward, the Pharmacy Quality Alliance (PQA), in 2019 that SUPD is a process measure based on the National Quality Forum's (NQF) criteria.

Comment: A few commenters that support CMS's proposal to modify the SUPD measure category to a process measure also noted that CMS should exercise caution when creating additional measures in the Star Ratings program or changing measure categorizations. Commenters were concerned that measure weights are being changed too rapidly. One commenter also expressed concerns with selecting the SUPD measure and recommends that CMS consider replacing SUPD with the Healthcare Effectiveness Data and Information Set (HEDIS) measure Statin Therapy for Patients with Diabetes (SPD).

Response: CMS thanks the commenters for this feedback. CMS carefully evaluates all of the measures incorporated in the Star Ratings. CMS will continue to monitor each of the

measures included in the Star Ratings as well as future measures incorporated into the Star Ratings. CMS also carefully evaluates the weights of each measure. The weights are based on measure type. Typically, CMS aligns the measure specifications with the measure steward. The Statin Therapy for Patients with Cardiovascular Disease (SPC) is already included in the Part C Star Ratings while the SUPD measure is included for Part D. CMS first discussed the HEDIS SPD and SPC measures, and the PQA SUPD measure in the 2016 Call Letter. As stated in the 2017 Call Letter, the SPD measure overlapped with the SUPD measure. Therefore, CMS added only one of the HEDIS measures (the Part C SPC measure) to the 2017 display page as well as the Part D SUPD measure after consideration of stakeholder feedback through the Call Letter process. CMS gained experience with calculating and reporting the measures and added SPC and SUPD to the Star Ratings as announced in the 2019 Call Letter.

Comment: Commenters provided feedback on the timeline proposed for reclassifying SUPD starting with the 2023 Star Ratings (using 2021 data). Some noted that SUPD is a process measure that has not changed in terms of specifications to warrant retaining SUPD as an intermediate outcome measure for the 2021 and 2022 Star Ratings. Additionally, commenters were concerned that retaining the classification as an intermediate outcome with a weight of 3, rather than immediately reclassifying SUPD as a process measure with a weight of 1, could lead to confusion, and is inconsistent with the guidance of expert measure developers, which could lead to instability for the Star Ratings. However, there were a few commenters who supported CMS's proposed timeline as it would take into consideration plan efforts and coordination needed to account for the SUPD measure reclassification.

Response: Reclassifying SUPD as a process measure (including its weight), is a substantive change that must be proposed and finalized through rulemaking as required by § 423.184(d)(2).

In the April 2018 final rule, CMS finalized the weight of 3 for SUPD for the 2021 and 2022 Star Ratings. In the February 2020 proposed rule, CMS proposed to reclassify SUPD as a process measure with a weight of 1 for future years, starting with the 2023 Star Ratings. This timeline and approach is consistent with the April 2018 final rule which outlined that a key tenet of the Star Ratings program is to make changes prior to the measurement year and to give sponsors enough lead time, in order to ensure greater transparency and stability for the Star Ratings program for plan sponsors.

Comment: A few commenters opposed reclassifying SUPD to a process measure or changing the weight of 3 to 1. Commenters noted that statin use for diabetic patients is an important and valuable intervention; thus, SUPD should remain classified as an intermediate outcome measure. Additionally, commenters were concerned with reclassifying SUPD and lowering the weight in the absence of outcomes-focused measures within the Star Ratings that address appropriate care for diabetes and cardiovascular care, given the strong correlation between the two conditions.

Response: CMS agrees that SUPD is an important measure that is included in the Star Ratings. Per NQF's definition of process measures, CMS agrees that prescribing a statin is a step in providing good care, rather than an outcome of such care. Furthermore, the measure steward, PQA, has classified SUPD as a process measure based on NQF's definition. As such, CMS proposed to reclassify SUPD as a process measure with a weight of 1 to align with the industry definitions.

Comment: Several commenters gave specific feedback regarding exclusion criteria related to SUPD, such as beneficiaries predisposed to statin intolerance or history of rhabdomyolysis. Commenters were concerned that only using prescription claims limited the types of exclusions included in SUPD. In addition, a few commenters noted this quality measure

does not reflect or capture achievable outcomes related to reversing chronic disease or decreasing cardiovascular morbidity and mortality.

Response: We thank the commenters for the feedback, but these comments are out of scope for this rule since the comments do not reference the reclassification of the SUPD measure and the subsequent change to the measure weight. CMS will share the measure specification comments with the measure steward, PQA, about the additional populations that were recommended for exclusion, the concerns with using prescription claims and exclusions, and to consider future measures on outcomes related to reversing chronic disease.

Comment: A commenter was concerned with the current COVID-19 public health emergency and how it could impact the accuracy of the measure.

Response: Thank you for this feedback. CMS will continue to monitor the impact of the public health emergency on the SUPD measure.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposal without modification. Starting with the 2023 Stars Rating, the SUPD measure will be reclassified as a process measure with a weight of 1. This change will be reflected in the Medicare Part C & D Star Ratings Technical Notes for the 2023 Star Ratings, which are based on the 2021 measurement period.

C. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

In the February 18, 2020 proposed rule (85 FR 9008), we proposed certain modifications to the medical loss ratio (MLR) regulations for the Medicare Part C and Part D programs.

Briefly, we proposed to amend § 422.2420(b)(2)(i) to allow MA organizations to include in the MLR numerator as “incurred claims” all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of “provider” as defined at § 422.2.

We also proposed to codify the definitions of partial, full, and non-credibility and credibility factors that we published in the May 2013 Medicare MLR final rule (78 FR 31295 through 31296). Finally, for MA medical savings account (MSA) contracts receiving a credibility adjustment, we proposed to apply a deductible-based adjustment to the MLR calculation in order to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles.

1. Background

An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. The proposed rule provided background on the Part C and Part D medical loss ratio (MLR) requirements, including the statutory and regulatory authority. The Part C statute, at section 1857(e)(4) of the Act, expressly imposes a minimum medical loss ratio requirement for MA plans. Because section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 2013 Medicare MLR final rule, which codified the MLR requirements for Part C MA organizations and Part D sponsors (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X. In the April 2018 final rule (83 FR 16440), we changed certain aspects of the MLR calculation and revised the reporting requirements.

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent

minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

2. Regulatory Changes to Incurred Claims (§ 422.2420)

Section 422.2420(a) of the regulations sets forth a high-level definition of the MLR as the ratio of the numerator, defined in paragraph (b), to the denominator, defined in paragraph (c). In general, MA costs are in the numerator and revenues are in the denominator. Section 422.2420(b)(1) identifies the three components of the MLR numerator for MA contracts that are not MSA contracts: (1) incurred claims (as defined in paragraphs (b)(2) through (4)); (2) the amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year; and (3) expenditures under the contract for activities that improve health care quality, which are described in detail at § 422.2430. For MA MSA contracts, the three components of the MLR numerator are (1) incurred claims (as defined in paragraphs (b)(2) through (4)); (2) expenditures under the contract for activities that improve health care quality; and (3) the amount of the deposit into the Medicare savings account for MSA enrollees. We proposed to revise the regulation text regarding the incurred claims portion of the numerator.

Under current § 422.2420(b)(2)(i), incurred claims include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services (described at paragraph (a)(2) of that section) that are provided to all enrollees under the contract. Section 422.2 defines a “provider” for purposes of the MA regulations as any individual or entity that is engaged in the delivery of health care services in a State and is licensed or

certified by the State to engage in that activity in the state, or to deliver those services if such licensing or certification is required by State law and regulation. Per § 422.2420(a)(2), “covered services” are the benefits defined at § 422.100(c): basic benefits, mandatory supplemental benefits, and optional supplemental benefits.

As explained in greater detail in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, we proposed revisions to the regulations at § 422.100 in order to codify subregulatory guidance and statutory changes that have expanded the types of supplemental benefits that MA plans may include in their plan benefit packages (PBPs). The proposed amendment to § 422.100(c)(2) would codify our longstanding interpretation of the statute to require a supplemental benefit to be an item or service (1) that is primarily health related; (2) for which the MA organization incurs a non-zero direct medical cost; and (3) that is not covered by Medicare Parts A, B, or D. In the 2019 Call Letter, issued on April 2, 2018, we announced that we had reinterpreted the scope of what would be “primarily health related” in order to meet this criterion to be a supplemental benefit. Under this reinterpretation, to be considered “primarily health related,” a supplemental benefit must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization; we explained in the contract year 2019 Call Letter how this means the benefit must focus directly on an enrollee’s health care needs and must be medically appropriate and recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one. As part of proposed § 422.100(c)(2), to account for the types of supplemental benefits that may be offered under the policy changes addressed in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, we also proposed specific

provisions to address permissible supplemental benefits that are not primarily health related and for which the non-zero direct cost incurred must be a non-administrative direct cost (if it is not a medical cost).

In § 422.102(f), as finalized in section II.A. of this final rule, we are codifying regulation text implementing amendments made by the BBA of 2018 to section 1852(a)(3) of the Act to expand the types of supplemental benefits that may be offered to chronically ill enrollees, starting in contract year 2020. Under paragraph (D) of section 1852(a)(3) of the Act, as added by the BBA of 2018, MA organizations may provide special supplemental benefits for the chronically ill (SSBCI) that are not primarily health related to chronically ill enrollees, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function.

As explained in the proposed rule, under current § 422.2420(b)(2)(i) of the MA MLR regulations, incurred claims in the MLR numerator include direct claims paid *to providers* for covered services furnished to all enrollees under an MA contract. The amendment to section 1852(a)(3)(D) of the Act has expanded the types of supplemental benefits that can be “covered services” under an MA plan. The amendments to implement that change at § 422.102(f) and the continuation of our policy for establishing what it means for a benefit to be primarily health related, both, mean that permissible supplemental benefits might include items and services that would not typically be furnished by an individual or entity that is a “provider” as defined at § 422.2. A provider, as defined in § 422.2, is an individual or entity engaged in the delivery of health care services and who is licensed or certified by the State to engage in that activity in the State. To ensure that amounts that an MA organization pays for covered services to individuals or entities that are not health care providers are included in incurred claims under current §

422.2420(b)(2)(i), we proposed to amend the regulation to remove the specification that incurred claims are payments to providers for covered services.

The proposed rule explained that, if incurred claims do not include amounts an MA organization pays to individuals or entities that are not providers for supplemental benefits, including SSBCI, these expenditures could still potentially be included in the MLR numerator as expenditures related to quality improvement activities (QIAs). To be considered a QIA under § 422.2430, a benefit must be an activity that falls into one or more of the categories listed in paragraph (a)(2) of that section, and it must be designed for the purposes listed in paragraph (a)(3): (1) to improve health quality; (2) to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) to be directed toward individual enrollees, specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) to be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. As explained in the proposed rule, although we believe that supplemental benefits that meet the expanded “primarily health related” standard at proposed § 422.100(c)(2)(ii)(A) and non-primarily health related SSBCI described at § 422.102(f) could potentially qualify as QIAs under § 422.2430, whether a particular benefit met all of the requirements of that regulation would need to be determined on a case-by-case basis. With our proposed amendments to § 422.2420(b)(2)(i), this case-by-case determination would no longer be necessary for services that are covered under the plan benefit package offered by an MA plan pursuant to the statute and regulations governing the MA program; all amounts paid for covered services would be included in the incurred claims portion of the MLR numerator.

As explained in the proposed rule, we believe that including in the MLR numerator amounts MA organizations spend on supplemental benefits that meet the “primarily health related standard” at proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under § 422.102(f), as amended in this final rule, is consistent with the purpose of the MA MLR requirement. As explained in the May 2013 Medicare MLR final rule adopting the MLR regulations (78 FR 31284), the MLR requirement creates an incentive for MA organizations to reduce administrative costs such as marketing costs, profits, and other uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

In order to ensure that the MLR numerator includes amounts MA organizations spend on supplemental benefits that are “primarily health related” under our current guidance and on non-primarily health related SSBCI under § 422.102(f), as adopted in this final rule, we proposed the following modifications to the regulation at § 422.2420(b)(2)(i):

- Remove the specification that incurred claims are direct claims that an MA organization pays *to providers* for covered services provided to all enrollees under the contract.
- Remove the specification that incurred claims include payments under capitation contracts *with physicians*.
- Replace the phrase “direct claims,” which customarily refers to billing invoices providers submit to payers for reimbursement, with the general term “amounts.”

As amended under our proposal, § 422.2420(b)(2)(i) would include in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2.

Including in incurred claims amounts spent on these expanded supplemental benefits, as proposed, avoids creating uncertainty over whether payments for such covered services could otherwise be included in the MLR numerator (for example, as QIA-related expenditures), and it is consistent with our determination in the May 2013 Medicare MLR final rule (78 FR 31289) that incurred claims should reflect the benefit design under the contract.

We received 27 comments on the proposed amendments to § 422.2420(b)(2)(i). The following is a summary of the comments we received on the proposal and our responses:

Comment: The majority of commenters supported the proposal. Many commenters believed that including in the MLR numerator as incurred claims all payments for covered services would provide greater certainty and reduce plan burden by eliminating the need to assess whether individual benefits meet the criteria to qualify as QIAs under § 422.2430. A number of commenters believed that the proposed change would encourage the expansion of supplemental benefits to address social barriers to care and MA enrollees' other health needs. A few commenters commended us for recognizing the role played by individuals and entities that are not providers in implementing the expanded supplemental benefit flexibility. A couple of commenters noted that they agreed with our view that including in incurred claims amounts spent on these expanded supplemental benefits is consistent with our prior determination that incurred claims should reflect the benefit design under the contract.

Response: We thank the commenters for their support. We reiterate that under our proposal and this final rule, only amounts expended by the MA organization for covered services, which must meet the standards of the MA program for coverage, can be included in the MLR numerator as incurred claims.

Comment: A commenter supported the proposal but requested that we clarify that the incurred claims portion of the MLR numerator will include capitated payments by MA organizations to clinical risk-bearing entities (for example, Independent Practice Associations (IPAs), Physician Hospital Organizations (PHOs), and Accountable Care Organizations (ACOs)) that include amounts for both medical and administrative services, provided the arrangement satisfies a four-factor test that was originally set forth in a guidance document²⁸ related to the MLR rules that apply to issuers of employer group and individual market private insurance (hereinafter referred to as the “commercial MLR rules”), and later incorporated into our annual MLR Data Form Filing Instructions for MA organizations and Part D sponsors. The commenter expressed concern that, if the four-factor test does not remain in place, all capitated payments to providers would need to be divided between medical services and delegated administrative services, and then aggregated up to the plan level to determine the amount to be excluded from the MLR as administrative costs.

Response: The amendment to § 422.2420(b)(2)(i), as proposed and finalized, includes in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2. This revision removes the specification that the recipient of a payment for a covered service must be a provider (or a physician, in the case of capitated payments) to be included in incurred claims. The proposed change would not, if finalized, exclude from the incurred claims portion of the MLR numerator any payments that could be included in the numerator as incurred claims under the current MLR rules. However, this amendment also does not authorize inclusion

²⁸ CCIIO Technical Guidance (CCIIO 2012—001): Questions and Answers Regarding the Medical Loss Ratio Interim Final Rule. February 12, 2012.

in the numerator of costs that are excluded from incurred claims, such as administrative expenses addressed in § 422.2420(b)(4).

The four-factor test referenced by the commenter has been incorporated into our annual MLR Data Form Filing Instructions (formerly the MLR Report Filing Instructions) (OMB control no. 0938-1232) (CMS-10476) for each contract year since contract year 2014. The instructions specify that amounts paid by an MA organization or Part D sponsor to clinical risk-bearing entities can be included in the MLR numerator as incurred claims if the following criteria are met:

- (1) The entity contracts with an issuer to deliver, provide, or arrange for the delivery and provision of clinical services to the issuer's enrollees but the entity is not the issuer with respect to those services;
- (2) The entity contractually bears financial and utilization risk for the delivery, provision, or arrangement of specific clinical services to enrollees;
- (3) The entity delivers, provides, or arranges for the delivery and provision of clinical services through a system of integrated care delivery that, as appropriate, provides for the coordination of care and sharing of clinical information, and which includes programs such as provider performance reviews, tracking clinical outcomes, communicating evidence-based guidelines to the entity's clinical providers, and other, similar care delivery efforts; and
- (4) Functions other than clinical services that are included in the payment (capitated or fee-for-service) must be reasonably related or incident to the clinical services, and must be performed on behalf of the entity or the entity's providers.

Payments to risk-bearing entities that include payments for administrative functions performed on behalf of the entity's member providers are incurred claims for purposes of § 422.2420 if all four factors outlined above are met.²⁹ However, to the extent that administrative functions are performed on behalf of the MA organization or Part D sponsor, that portion of the organization's or sponsor's payment that is attributable to administrative functions may not be included in incurred claims. This is the case regardless of whether payment is made according to a separate, fee-for-service payment schedule or as part of a global, capitated fee payment for all services provided.³⁰ We will continue to use this four-factor test to determine whether an MA organization can include payments to clinical risk-bearing entities.

Comment: A commenter expressed concern that the proposed changes to the definition of "incurred claims" could be interpreted as sufficiently broad to permit MA plans and PDPs to include in the MLR numerator costs associated with pharmacy benefit manager (PBM) services due to the nexus between those services and beneficiary access to covered drugs. The commenter was concerned in particular that the proposed change would allow MA organizations and Part D sponsors to include costs for implementing utilization management tools and strategies in the MLR numerator as incurred claims.

Response: We appreciate the commenter's concerns. Amending § 422.2420(b)(2)(i) as proposed to include in incurred claims amounts paid for covered services, regardless of whether

²⁹ For example, a bundled payment to an Independent Practice Association (IPA) or similar entity for providing clinical services to enrollees which includes: the IPA processing claims payments to its member providers and submitting claims reports to issuers on behalf of its providers; performing provider credentialing to determine a provider's acceptability into the IPA network; and developing a network for its providers' benefit, can be included in incurred claims.

³⁰ For example, payment for processing claims in order to issue explanations of benefits (EOBs) to enrollees and handling any stage of enrollee appeals cannot be included in incurred claims. Payments for non-clinical services for which the contract between the clinical risk-bearing entity, such as an IPA, and the MA organization or Part D sponsor contains a "clawback" provision are not considered incurred claims for MLR reporting purposes.

the payment is made to a provider, does not allow MA organizations or Part D sponsors to include in the MLR numerator amounts that are identified as non-claims costs and excluded from incurred claims under our current rules. These non-claims costs that continue to be excluded from the MLR numerator include amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management (§ 422.2420(b)(4)). We note, however, that our current rules permit a clinical-risk bearing entity's costs related to utilization management and other administrative services to be included in incurred claims if all four factors outlined in the previous response are met. In addition, consistent with CCIIO's Technical Guidance,³¹ our MLR Data Form Filing Instructions³¹ specify that when a third party vendor, through its own employees,³² provides clinical services directly to enrollees, the entire portion of the amount the issuer pays to the third party vendor that is attributable to the third party vendor's direct provision of clinical services should be considered incurred claims, even if such amount includes reimbursement for administrative costs directly related to the vendor's direct provision of clinical services.³³

Comment: A commenter opposed the proposal because they believed that including all payments for covered services in the incurred claims portion of the MLR numerator would be an unnecessary and inappropriate deviation from the commercial MLR rules, which only include payments to non-providers in the MLR numerator if they meet the requirements for QIA-related

³¹ See, for example, the May 13, 2011 CCIIO Technical Guidance (CCIIO 2011-002), Q&A #12, available at: <https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf>.

³² The term "through its own employees" does not include a third party vendor's contracted network of providers because such network providers are not considered employees of the third party vendor.

³³ The MLR Data Form Filing Instructions include the example of a Part D sponsor that contracts with a pharmacy benefit manager (PBM) to provide clinical services directly to enrollees through a mail order pharmacy. The instructions explain that the sponsor's payments to the PBM for mail order pharmacy services provided directly by the PBM's employees, including administrative costs related to the PBM's direct provision of such mail order pharmacy services, would be included in the sponsor's incurred claims.

expenditures. The commenter expressed approval for the approach we took in the May 2013 Medicare MLR final rule, which was to use the commercial MLR rules as a reference point for developing the MLR rules for Medicare Advantage and Part D (hereinafter referred to as the “Medicare MLR rules”) and to only depart from the commercial rules to extent necessary and appropriate given the Medicare context (78 FR 31285, 31290). The commenter stated the proposed rule did not identify any reason that the Medicare context makes it necessary and appropriate to depart from the requirement in the commercial MLR rules that incurred claims be paid to providers for covered services. The commenter asserted that the Medicare context does not meaningfully differ from the commercial context with respect to the benefits at issue.

Response: We respectfully disagree with the commenter. We continue to believe that it is important that we align the Medicare MLR rules with the commercial MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. However, as stated in the February 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (78 FR 12428 through 12429) (hereinafter referred to as the “February 2013 Medicare MLR proposed rule”), we also recognize that the commercial MLR rules may need to be revised in order to fit unique characteristics of the MA and Part D programs. We believe that it is appropriate that we depart from the commercial MLR rules and expand the meaning of “incurred claims” to include covered services furnished by individuals and entities that are not providers, as proposed. The amendment to section 1852(a)(3)(D) of the Act by the BBA of 2018 to expand the types of supplemental benefits that can be “covered services” under an MA plan and the implementation of that change at § 422.102(f), as well as CMS’ reinterpretation of what it means

for a supplemental benefit offered by an MA plan to be primarily health related, mean that permissible supplemental benefits might include items and services that would not be furnished by a “provider” as defined at § 422.2. As we explained in the contract year 2019 Call Letter, a benefit is primarily health related if it diagnoses, prevents, or treats an illness or injury, compensates for physical impairments, acts to ameliorate the functional or psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization; and while we indicated that supplemental benefits must be medically appropriate and recommended by a licensed provider, we acknowledged that they might not be directly provided by a health care professional. Because SSBCI are only required to have a reasonable expectation of maintaining or improving the health or overall function of the chronically ill enrollee and are not required to be primarily health related, we believe those benefits can be provided by someone who is not a health care professional. We are concerned that uncertainty about whether payments for these benefits can be included in the MLR numerator may make MA organizations less inclined to include them in their plan offerings. We believe that it is contrary to Congress’ intent in amending section 1852(a)(2)(D) of the Act, and that it undermines CMS’ efforts to provide MA organizations with additional flexibility to meet beneficiaries’ health needs through supplemental benefits, if the MLR fails to adapt to changes in the permissible benefit design and ultimately deters MA organizations from offering those benefits. In addition, we note that section 2718 of the Public Health Service Act specifies that commercial MLRs shall reflect the percentage of total premium revenue spent “on reimbursement for clinical services provided to enrollees,” QIAs, and non-claims costs (which are excluded from the MLR numerator). By contrast, section 1857(e)(4) of the Act, which sets forth the minimum MLR requirement for the MA program, does not require that the portion of the MLR numerator consisting of non-QIA

expenditures should be for “clinical services” or otherwise specify how the Secretary should calculate Medicare MLRs. Although the commercial and Medicare MLR requirements were both created by the Affordable Care Act of 2010, the statute gives the Secretary greater flexibility in determining how to integrate an MLR requirement into the Medicare program. We continue to use this flexibility to revise the calculation of the Medicare MLR as appropriate based on the unique characteristic of the MA and Part D programs, and we believe that amendment here is such an appropriate change.

Comment: A commenter believed that the proposed change was both unnecessary and unlikely to be effective as a means of encouraging MA organizations to expand their supplemental benefit offerings. The commenter cited data showing that MA organizations had been increasing their supplemental benefit offerings in recent years, which the commenter attributed to previous rule changes. The commenter recommended that instead of adjusting the MLR calculation to encourage the expansion of coverage of supplemental benefits, we should address the barriers to providing supplemental benefits that have been identified by MA organizations - specifically, upfront costs, trade-offs among benefits, return on investment, and provider availability. The commenter cautioned that the proposal may have unintended, negative impacts on non-supplemental benefit coverage, but the commenter did not specify what it meant by non-supplemental benefit coverage or what those negative impacts might be.

Response: We thank the commenter for their feedback and recommendations. As indicated in our response to other comments, we proposed to revise the meaning of “incurred claims” to include payments for covered services furnished by individuals or entities that are not providers as defined at § 422.2 in order to avoid creating uncertainty about whether expenditures for supplemental benefits can be included in the MLR numerator, which might deter MA

organizations from offering those benefits. Although the purpose of our proposal was not to give MA organizations an incentive to offer expanded supplemental benefits, as noted above, we did receive numerous comments, some of which were submitted by MA organizations, which expressed support for the proposed change because the commenters believed it would encourage plans to offer expanded supplemental benefits. Our efforts to change how supplemental benefits are accounted for in the MLR numerator do not preclude us from pursuing other opportunities that are appropriate for CMS to take to promote the expansion of supplemental benefits.

Comment: A commenter requested that we clarify in final rulemaking the review and enforcement actions we undertake to ensure that QIA is not abused at the expense of MA enrollees. Another commenter requested that we closely examine all MA activities that are currently categorized as QIA to ensure that their utilization improves quality.

Response: At present, we do not actively collect information on MA organizations' QIA expenditures. As a result of change to the MLR reporting requirements finalized in the April 2018 final rule (83 FR 16674), MA organizations are not required to include in their annual MLR submissions information on their QIA expenditures. We have the authority under § 422.2480 to conduct selected audit reviews of the data reported under § 422.2460, which includes the capability to request detailed data regarding the QIA expenditures included in the Medicare MLR, in order to determine that the MLR and remittance amounts were calculated and reported accurately, and that sanctions were appropriately applied. MA organizations are required to attest to the accuracy of the MLR data submitted. In addition, we note that MA organizations and Part D sponsors are required to submit and attest to the data that details their spending on enrollee health care services as part of their annual bids.

Comment: Several commenters requested that we expand our proposal to include in incurred claims all expenditures related to combating COVID-19.

Response: The commenters did not provide specific information on the types of expenditures they wish to make that they believe would not already be included in the MLR numerator as incurred claims under our proposal. Without more detailed information, we are unable to determine whether including the expenditures that the commenters are contemplating in incurred claims would in fact necessitate a modification to our proposal, or whether there is logical outgrowth to make such a modification or whether it is consistent with our overall policies on the Medicare MLR.

Comment: We received several recommendations for additional changes to the MLR requirements that are outside the scope of this final rule. A commenter recommended that we delay implementation of the MLR enrollment sanctions for contracts that fail to meet the MLR requirement for three consecutive contract years; that we develop a fixed quality improvement (QI) rate that could be added to the MLR numerator, similar to what is permitted under the commercial MLR regulations (45 CFR 158.221(b)(8)); that we provide guidance to plan sponsors concerning corrections of prior MLR submissions when errors are found that impact remittance calculations and that we develop a process to correct such data; and that we not apply the MLR requirements to standalone Part D plans. A commenter recommended that we mandate in the final rule that Part D sponsors must utilize a system to apply direct and indirect remuneration (DIR) fees at the point of sale as a means of improving the accuracy of the reported MLRs.

Response: We thank the commenters for their recommendations and will consider whether they are appropriate to address through future rule-making or other guidance.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposal without modification.

3. Codifying Current Definitions of Partial, Full, and Non-credibility and Credibility Factors (§§ 422.2440 and 423.2440)

The regulations at §§ 422.2440 and 423.2440 provide for the application of a credibility adjustment to the medical loss ratios (MLRs) of certain MA and Part D contracts with relatively low enrollment. A credibility adjustment is a method to address the impact of claims variability on the experience of smaller contracts by adjusting the MLR upward. As discussed in the February 2013 Medicare MLR proposed rule (78 FR 12438), for contracts with fewer members, random variations in the claims experience of enrollees could cause a contract's reported MLR to be considerably below or above the statutory requirement in any particular year, even though the MA organization or Part D sponsor estimated in good faith that the combination of the projected revenues and projected claims would produce an MLR that meets the statutory 85 percent minimum MLR requirement. The MLR credibility adjustments address the effect of this random variation by increasing the MLR of smaller contracts, thereby reducing the probability that such contracts will fail to meet the minimum MLR requirement simply because of random claims variability.

Whether a contract receives a credibility adjustment depends on the extent to which the contract has credible experience. A contract with credible experience is one that covers a sufficient number of beneficiaries for its experience to be statistically valid. A contract with fully credible experience has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error and will not receive a credibility adjustment under §§ 422.2440(b) and 423.2440(b). A contract has non-credible experience if it has so few

beneficiaries that it lacks valid data to determine whether the contract meets the MLR requirement. Under §§ 422.2440(c) and 423.2440(c), a contract with non-credible experience is not subject to sanctions for failure to meet the 85 percent MLR requirement. A contract has partially credible experience if it exceeds the enrollment threshold for non-credible experience but does not have a sufficient number of enrollees for its experience to be fully credible. For contracts with partially credible experience, a credibility adjustment adds additional percentage points to the MLR in recognition of the statistical unreliability of the underlying data.

In the May 2013 Medicare MLR final rule (78 FR 31295 through 31296), CMS published the definitions of partial, full, and non-credibility and the credibility factors for partially credible MA and Part D contracts for contract year 2014. The factors appeared in that final rule in Tables 1A (finalized here as Table 1 to § 422.2440) and 1B to (finalized here as Table 1 to § 423.2440). Consistent with that final rule and regulations at §§ 422.2440 and 423.2440, for contract years 2015 through 2020, we finalized through the annual Advance Notice and Rate Announcement process the continued use of these definitions and credibility factors.

As explained in the proposed rule, we believe that the definitions of partial, full, and non-credibility and the credibility factors published in the May 2013 Medicare MLR final rule continue to appropriately address the effect of random claims variability on the MLRs of low enrollment MA and Part D contracts. However, we believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to defining and publishing these terms

and factors through the annual Advance Notice and Rate Announcement process. Therefore, we proposed to amend our regulations at §§ 422.2440 and 423.2440 to codify the definitions of partial, full, and non-credibility and the credibility factors that we published in the May 2013 Medicare MLR final rule (78 FR 31296).

We proposed to amend paragraph (d) of §§ 422.2440 and 423.2440 by removing the current text (which states that CMS will define and publish definitions of partial, full, and non-credibility and the credibility factors through the annual Advance Notice and Rate Announcement process) and adding new paragraphs (d)(1) through (3) to specify ranges for the number of member months at which a contract's experience is, respectively, partially credible, fully credible, or non-credible. We proposed that the number of member months at which a contract's experience is defined as partially credible, fully credible, or non-credible be the same as the values that were used define each of those terms in the May 2013 Medicare MLR final rule. Thus, for MA contracts, we proposed that a contract is partially credible if it has at least 2,400 member months and fewer than or equal to 180,000 member months, fully credible if it has more than 180,000 member months, and non-credible if it has fewer than 2,400 member months. For Part D contracts, we proposed that a contract is partially credible if it has at least 4,800 member months and fewer than or equal to 360,000 member months, fully credible if it has more than 360,000 member months, and non-credible if it has fewer than 4,800 member months. We proposed to amend §§ 422.2440 and 423.2440 by removing from paragraphs (a) and (b) of both sections the text which indicates that CMS determines whether a contract's experience is partially credible or fully credible, respectively, and by adding at paragraphs (a), (b), and (c) of both sections new language specifying that partially credible experience is defined

at (d)(1), fully credible experience is defined at (d)(2), and non-credible experience is defined at (d)(3).

At § 422.2440, we proposed to add new paragraph (e) to address the credibility adjustment for partially credible contracts. We proposed at paragraph (e)(1) that, for partially credible MA contracts other than MSA contracts, the credibility adjustment is the base credibility factor determined under proposed paragraph (f). At new paragraph (f), we proposed to specify that the base credibility factor for a partially credible MA contract is determined based on the number of member months and the factors in Table 1 to § 422.2440. New paragraph (f) also states the rules for using Table 1 to § 422.2440 to identify the base credibility factor: (i) when the number of member months for a partially credible MA contract exactly matches the amount in the “Member months” column in Table 1 to § 422.2440, the value associated with that number of member months is the base credibility factor; and (ii) the base credibility factor for a number of member months between the values shown in Table 1 to § 422.2440 is determined by linear interpolation.

At § 423.2440, we proposed to add new paragraph (e), which provides that, for partially credible Part D contracts, the applicable credibility adjustment is determined based on the number of member months and the factors in Table 1 to § 423.2440. New paragraph (e) states the rules for using Table 1 to § 423.2440 to identify the base credibility factor: (1) when the number of member months used to determine credibility exactly matches a member month category listed in Table 1 to § 423.2440, the value associated with that number of member months is the credibility adjustment; and (2) the credibility adjustment for a number of member months between the values shown in Table 1 to § 423.2440 is determined by linear interpolation.

We received no comments on this proposal and are finalizing this provision without modification for the reasons outlined in the proposed rule.

4. Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

We proposed to include in the MLR calculation an additional adjustment factor for MA medical savings account (MSA) contracts that receive an MLR credibility adjustment.

Specifically, we proposed that the credibility adjustment for partially credible MA MSA contracts will be calculated by multiplying the applicable base credibility factor in Table 1 to § 422.2440 by a “deductible factor.” This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but with a low average deductible. As under the commercial MLR rules, the proposed deductible-based adjustment would only apply to contracts that receive a credibility adjustment due to low enrollment. We believe that a contract with experience that is fully credible has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error, regardless of the deductible level.

In the February 2013 Medicare MLR proposed rule (78 FR 12428), we explained that we used the commercial MLR rules as a reference point for developing the Medicare MLR rules. We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. However, we recognized that some areas of the commercial MLR rules would

need to be revised to fit the unique characteristics of the MA and Part D programs. One way in which the Medicare MLR rules currently deviate from the commercial rules is the omission of a deductible-based adjustment to the Medicare MLR calculation. The rationale given in the February 2013 Medicare MLR proposed rule for omitting a deductible factor from the Medicare MLR calculation was that Medicare deductibles were more confined than deductibles in the commercial market, and that we believed that the limited range of Medicare cost sharing did not prompt the need for such an adjustment (78 FR 12439).

As explained in the proposed rule, although we continue to believe that deductibles for most MA and Part D contracts are too low to necessitate the adoption of a deductible factor for all contracts, we now recognize that the February 2013 Medicare MLR proposed rule's rationale for excluding a deductible factor from the Medicare MLR calculation did not adequately take into account the specific characteristics of MA MSA plans, which tend to have much higher deductibles than other MA plan types. For contract year 2020, the average deductible is \$454 for MA plans (excluding MA MSAs) and \$6,000 for MA MSAs. The proposed rule noted that, under the commercial MLR regulations at 45 CFR part 158, a deductible factor applies to the credibility adjustment of issuers of employer group and private health insurance plans that have an average deductible of \$2,500 or higher. For contract year 2020, all MA MSAs have deductibles in excess of \$2,500. These significantly higher deductibles in MSA plans cause MA MSA contracts to have more variability in their claims experience relative to MA contracts with the same number of enrollees but lower deductibles. In light of this information, we believe that it is clear that our policy of excluding a deductible factor for MA MSA contracts should be revisited.

Further, to the extent that this variability in claims experience and its potential impact on the MLR calculation has deterred MA organizations from offering an MSA product, the proposed addition of a deductible factor to the MLR calculation for MA MSAs would serve to encourage the offering of MA MSA plans by eliminating the current inconsistency in how the commercial and Medicare MLR rules take into account the greater variability of claims experience under health insurance policies with high deductibles. The proposed rule noted that our proposal to add a deductible factor to the MLR calculation for MA MSA contracts aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation’s Seniors (October 3, 2019) for the Secretary to take actions that “encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . .*” (emphasis added). The proposed rule also noted that, for many Medicare beneficiaries, the greatest barrier to enrolling in an MA MSA has been the lack of MA MSA plans in the beneficiary’s area of residence. For contract year 2020, MA MSA plans are only available in 27 states and the District of Columbia. The omission of a deductible-based adjustment from the current Medicare MLR regulations could contribute to the limited availability of MA MSAs for Medicare beneficiaries because the greater variability in the MLR for contracts with high average deductibles – and the resulting higher risk of a potential remittance to CMS or sanctions under § 422.2410 – could dissuade MA organizations from offering plans of this type. We noted in the proposed rule our belief that finalizing a deductible factor for MA MSAs would make it less likely that MA organizations would be deterred from offering MA MSA plans out of concern that the MA MSA contract would be at risk of failing to meet the MLR requirement due to random variations in claims experience.

We proposed to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158. As noted in the December 1, 2010 Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule (75 FR 74881 through 74882), the commercial deductible factors were based on an actuarial analysis of anticipated claims experience in the commercial market by actuarial consultants to the National Association of Insurance Commissioners (NAIC). We explained in the proposed rule that we would prefer to use Medicare data to develop the deductible factors that apply to MA MSAs, and that we intend to assess the feasibility of using Medicare data for this purpose. We noted in the proposed rule and continue to believe that the commercial deductible factors are suitable for adjusting MSA MLRs in the absence of Medicare-specific deductible factors because the commercial factors are designed to take into account the variability in claims experience resulting from similarly high deductibles. We proposed to apply the commercial deductible factors in the MLR calculation for MA MSAs. We solicited comment on whether and how Medicare data should be used to evaluate whether the difference in variability between MLRs for MSA plans and non-MSA plans necessitates the use of Medicare-specific deductible factors, as well as how Medicare data could be used to develop Medicare-specific deductible factors. We also solicited comment on whether and how the proposed deductible factors should be adjusted to account for any unique features of the Medicare MLR rules (for example, the inclusion of the MA MSA deposit amount in the Medicare MLR numerator and denominator), or to reflect any differences between the commercial and Medicare MLR rules (such as the commercial rules' lower minimum MLR requirement for small group and individual health insurance plans (80 percent, compared to the Medicare rules' 85 percent MLR requirement for all contracts)). We solicited comment on

potential consequences of the application of a deductible factor to the MLR calculation for MA MSA contracts, such as impacts on benefits for enrollees in MSA plans.

We proposed new § 422.2440(e)(2) to specify that the credibility adjustment for an MA MSA contract would be the base credibility factor determined under new paragraph (f), multiplied by the deductible factor determined under new paragraph (g). At new paragraph (g), we proposed to specify that the applicable deductible factor for an MA MSA contract would be based on the enrollment-weighted average deductible for all MSA plans under the contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract during the contract year for which the MLR is being calculated. (We note that all MA plans under an MA MSA contract must be MSA plans, and MSA plans may only be offered under MSA contracts.) When the weighted average deductible for a contract exactly matches the amount in the "Weighted average deductible" column in Table 2 to § 422.2440, the value associated with that weighted average deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 to § 422.2440 is determined by linear interpolation.

We received 5 comments on the proposal to add a deductible factor to the MLR calculation for MA MSAs. The following is a summary of the comments we received on the proposal and our responses:

Comment: A commenter supported the proposal. The commenter expressed hope that adding a deductible factor to the MLR calculation for MA MSA contracts would lead to the greater availability of MA MSA products in the marketplace, which the commenter believed would be an attractive option for many consumers.

Response: We thank the commenter for their support.

Comment: A commenter stated that they do not support policies that single out high-deductible health plans for preferential MLR treatment for the purpose of encouraging beneficiaries to enroll in such plans.

Response: We appreciate the commenter's objection to MLR policies that favor certain plan types over others. However, we disagree with the commenter's characterization of the proposed application of a deductible factor to the MLR calculation for certain MSA contracts as a form of preferential treatment. As explained in the proposed rule and summarized here, we believe an additional adjustment to the MLR calculation for MSA contracts is appropriate because the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. This is the case because high-deductible health plan enrollees' medical expenses must exceed a higher threshold before the plan begins to incur claims costs that can be included in the MLR numerator. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but a low average deductible. The deductible factor, which functions as a multiplier on the credibility adjustment factor, is calibrated so that the probability that a contract will fail to meet the MLR requirement is the same for all contracts that receive a credibility adjustment, regardless of the deductible level. Because the deductible factor is intended to mitigate the increased likelihood that a contract with a high deductible will fail to meet the MLR requirement due to random variations in claims experience, we believe that its application to the Medicare MLR calculation for MSA contracts serves to level the playing field for all MA contract types. We believe that the absence of a

deductible factor from the current regulations unduly penalizes MSA contracts and that adding a deductible factor removes this potential deterrent to the offering of MSAs.

Comment: Three commenters opposed the proposal because they objected to CMS giving MA organizations an incentive to enroll beneficiaries in high deductible health plans such as MSAs. A commenter expressed concern that beneficiaries may enroll in these plans due to their low premiums and tax benefits, without realizing that they could be responsible for thousands of dollars of pre-deductible costs should they need significant medical attention. Another commenter warned that Medicare beneficiaries have limited incomes and frequently experience chronic conditions, the proliferation of high-deductible MSAs among this vulnerable population could have catastrophic effects on beneficiary health, as enrollees forego care to avoid paying high out-of-pocket costs. A couple of commenters cited research which suggests that although high deductible plans reduce costs, this may be attributable to a decrease in utilization of necessary medical services or to high deductible plans enrolling younger, healthier members.

Response: We appreciate the commenters' concerns. Expanding access to MSAs so that Medicare beneficiaries who see the advantages in enrolling in a high-deductible plan have the option of doing so is a priority of the Trump administration. As discussed in the proposed rule, the proposal to add a deductible factor to the MLR calculation for MA MSA contracts aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) for the Secretary to take actions that "encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . .*" (emphasis added).

We note that the research cited by the commenters is mostly based on the experience of enrollees in high-deductible health plans operating outside of the Medicare context. We believe

that the widespread availability of zero premium MA plans makes it less likely that Medicare beneficiaries will enroll in high deductible plans due to the low premiums and tax benefits without adequately considering their potential out of pocket liability. In addition, there are protections to ensure that MSA enrollees have information that enables them to assess the coverage provided by MSA plans. Section 1852(c)(1)(B) of the Act and § 422.111(b)(2)(ii) require that MSA plans disclose, in clear, accurate, and standardized form to each enrollee at the time of enrollment and at least annually thereafter, a comparison of the benefits under the plan with benefits under other MA plans.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposal without modification.

V. Codifying Existing Part C and D Program Policy

A. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible with reasonable promptness to each individual electing the plan within the plan service area. This is generally implemented at § 422.112(a), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. In the April 15, 2010, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program Final Rule (75 FR 19691), CMS added criteria at § 422.112(a)(10) for determining whether an MA plan network is adequate and meets the statutory standard by codifying that MA plans must have networks that are consistent with the prevailing community pattern of health care delivery in the service area. The regulation provides that CMS will consider factors that make up the community patterns of health care, which CMS will use as a benchmark in evaluating MA plan networks, and lists certain examples of those factors in § 422.112(a)(10)(i) through (v). CMS explained in the October 22, 2009, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (74 FR 54644) that it would develop an automated system for reviewing network adequacy based on the elements that define community patterns of health care delivery and that we would define through subregulatory guidance how CMS would operationalize these factors.

Since that time, CMS has routinely provided subregulatory guidance to MA organizations that defines how CMS measures and assesses network adequacy.³⁴ We built the Network Management Module (NMM) in HPMS to facilitate automated reviews of plan networks and to annually transmit information to MA plans about provider/facility specialty types that are subject to maximum time and distance standards, minimum number requirements, and other critical information needed for the network adequacy reviews. The NMM also gave existing MA organizations and new applicants to the MA program the opportunity to routinely test their networks against our standards. Currently, we require that organizations contract with a sufficient number of specified providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. We update and refine the data and information that feed into network adequacy measures and perform analyses as needed. It is important that CMS ensure that MA organizations maintain an adequate network of contracted providers that are capable of providing medically necessary covered services to beneficiaries, both to ensure compliance with section 1851(d) of the Act and to protect beneficiaries. The network adequacy rules protect beneficiaries by ensuring that most, if not all, of the beneficiaries enrolled in a plan have access to providers within a reasonable time and distance from where the beneficiaries reside.

In this final rule, we are codifying existing network adequacy standards to provide MA organizations with a greater understanding of how CMS measures and assesses network adequacy by adding a new regulation at § 422.116. Specifically, we are codifying in § 422.116 the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards, minimum number requirements,

³⁴ See “Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance” - <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index>.

and exceptions. The regulation also addresses CMS's annual publishing of the Provider Supply file and Health Service Delivery (HSD) reference file to release updated numbers and maximums for these standards in subsequent years. The final regulation reflects modifications from our current network adequacy policy to further account for access needs in all counties, including rural counties, and to take into account the impact of telehealth providers in contracted networks. Section 1876(c)(4) of the Act imposes similar requirements for cost plans offered under section 1876 of the Act to make Medicare-covered services available and accessible to each enrollee with reasonable promptness when medically necessary. Under this authority, we are also amending § 417.416(e) to require 1876 cost organizations to also comply with the network adequacy standards described in § 422.116. A summary of our proposal follows.

1. General Provisions

We proposed in § 422.116(a) that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and the rules in new § 422.116. We also proposed that when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year. We explained that we would require such attestation in the MA organization's application or contract for a given year, but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

We cross-referenced § 422.114(a)(3)(ii) to identify the network-based plan types that would be subject to these network adequacy requirements. Network-based MA plans include all

coordinated care plans in § 422.4(a)(1), network-based MA private-fee-for-service (PFFS) plans in § 422.4(a)(3), and 1876 cost organizations. Generally, network-based MA medical savings account (MSA) plans are considered coordinated care plans in accordance with § 422.4(a)(1)(iii)(D), which includes “other network plans” as a type of coordinated care plan. However, since MSA plans do not require contracted networks, we proposed to exclude MSA plans from the requirements in § 422.116. By cross-referencing § 422.114(a)(3)(ii), we carved out an MA regional plan that meets access requirements substantially through deemed contracting, so local and regional PFFS plans operating in CMS defined network areas must meet CMS network adequacy requirements at § 422.116.

We proposed, at paragraph (a)(2), to codify the general rule underlying § 422.116 that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility specialty type, with each contract provider type within maximum time and distance of at least one beneficiary (in our MA Medicare Sample Census) in order to count toward the minimum number. The location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards. The minimum number criteria and the time and distance criteria vary by the county type. We proposed to establish the specific provider and facility types; county types; specific time and distance standards by county designation; and specific minimum provider number requirements in paragraphs (b), (c), (d) and (e), respectively, of § 422.116. Regardless of whether CMS evaluates a plan’s network against the access and adequacy standards in a given year, a plan’s network must meet these standards and will be held to full compliance with the standards. At paragraphs (a)(3) through (4), we proposed to codify additional general rules about the network adequacy requirements in this section. At paragraph

(a)(3), we proposed general rules for which provider types are not counted in evaluating network adequacy. In paragraph (a)(4), we proposed to codify certain administrative practices we have instituted over the past several years. Specifically, we proposed to annually update and make available Health Service Delivery (HSD) reference files in advance of our review of plan networks. These HSD files contain the minimum provider and facility number requirements, minimum provider ratios, and the minimum time and distance standards. We also proposed that we would annually update and make available a Provider Supply file that identifies available providers and facilities with office locations and specialty types. The Provider Supply file is updated annually based on information from the Integrated Data Repository (IDR), which has comprehensive claims data, as well as information from public sources. We may also update the Provider Supply file based on its findings from validation of provider information.

2. Provider and Facility Specialty Types

We proposed to codify at § 422.116(b) the list of provider and facility specialty types that have been subject to CMS network adequacy standards in the past, as not all specialty types are included in network adequacy reviews. We identified and proposed to codify the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area. We identified these provider and facility specialty types as critical to providing services based on review of Medicare FFS) utilization patterns, utilization of provider/facility specialty types in Medicare FFS and managed care programs, and the clinical needs of Medicare beneficiaries. We proposed to codify at § 422.116(a)(3) existing policy on the provider and facility types that are not counted in evaluating network adequacy: specialized, long-term care, and pediatric/children's hospitals and providers and facilities contracted with the organization only for its commercial, Medicaid, or other non-MA plans. In paragraph (a)(3), we

also proposed that hospital-based dialysis may count in network adequacy criteria for the facility type of Outpatient Dialysis. We clarified that primary care providers, the first provider specialty in our proposed list in paragraph (b)(1), are measured as a single specialty by combining provider specialty codes (001-006) in the HSD reference file.

Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for Opioid Use Disorder treatment services furnished by Opioid Treatment Programs (OTPs) on or after January 1, 2020. OTPs provide medication-assisted treatment for people diagnosed with an Opioid Use Disorder and must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an independent, SAMHSA-approved accrediting body. We did not propose to include OTPs as a facility type in § 422.116(b)(2) and explained it was due to the newness of the benefit and that we may consider adding OTPs to the facility type list in future proposals. However, we reminded MA organizations that they are required to pay for medically necessary care from certified OTPs.

We proposed at § 422.116(b)(3) that CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. For example, in the past CMS removed oral surgery as a provider specialty type from the HSD reference file, and replaced home health and durable medical equipment with an attestation in its application about the plan's network ensuring access to providers of these types. We proposed at § 422.116(a)(1) to require an MA plan to submit an attestation when required by CMS. We explained that we would require an MA organization to complete an attestation that it has an adequate network that provides the required access to and availability of provider specialty or facility types even where we do not evaluate access ourselves. Network adequacy criteria are measured for each individual specialty type and do not

roll up into an aggregate score. Therefore, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and use of an attestation in lieu of evaluation will permit us some necessary flexibility. In light of the lack of change to the list we have used over the past several years, we did not propose any means for CMS to add new provider specialty or facility types to the network adequacy evaluation without additional rulemaking.

3. County Type Designations

We proposed at § 422.116(c) to codify our current policy regarding county designations. Network adequacy is assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations). These metrics provide the means by which the various network adequacy criteria are differentiated to represent large geographic variations across the United States and its territories. They are based on the population size and the population density of each county.

We proposed to codify at § 422.116(c) the five county type designations using population size and density parameters that were identified in Table 6 in the proposed rule (85 FR 9094). Under our proposal, a county must meet both the population and density parameters for inclusion in a given county type designation and we explained that the proposed parameters are consistent with those we have used in conducting network adequacy reviews in prior years. We explained that we based the parameters on approaches used by the United States Census Bureau in its classification of "urbanized areas" and "urban clusters," and by the Office of Management and Budget (OMB) in its classification of "metropolitan" and "micropolitan." To calculate

population density at the county level, we divided the latest county-level population³⁵ estimate by the land area³⁶ for that county. We also stated that our county designation methodology was designed specifically for MA network adequacy and may not be appropriate for other purposes.

4. Maximum Time and Distance Standards and Customization

We proposed in § 422.116(a)(2) that network adequacy is measured using both maximum time and distance standards and minimum number requirements that vary by county type. In § 422.116(d), we proposed that CMS determines maximum time and distance standards by county type and specialty type and publishes these standards annually in the HSD Reference file. Maximum time and distance standards are set by county designation, referred to as the “base” time and distance standards, or by a process referred to as “customization.” We proposed to codify the base time and distance standards by county designation that are in current practice with recent network reviews and included the standards in Table 7 of the proposed rule (85 FR 9095) as well as in the proposed regulation text as Table 1 to paragraph (d)(2). We also explained in greater detail how the specific time and distance standards we proposed for each provider and facility type and county designation were developed and refer readers to the proposed rule for that discussion (85 FR 9097).

As explained in the proposed rule, we have added flexibility in recent years to expand the time (in minutes) and distance (in miles) standards beyond the base standards in cases where, due to a shortage of supply of providers or facilities, it is not possible to meet the base time and

³⁵ United States Census Bureau. American Factfinder. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2018: 2018 Population Estimates. Retrieved from: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPANNRES&src=pt

³⁶ United States Census Bureau. American Factfinder. Population, Housing Units, Area, and Density: 2010 - United States -- County by State; and for Puerto Rico: 2010 Census Summary File 1. Retrieved from: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_GCTPH1.US05PR&prodType=table

distance standards. We proposed to codify this flexibility and the process for using it at § 422.116(d)(3) and refer to it as “customization.” To customize distance standards, we use software to map provider location data from the Provider Supply file against the population distribution data in CMS’s MA Medicare Sample Census.³⁷ For each specialty and county where there are insufficient providers within the base distance standard, we use mapping results to identify the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type. The resulting distance is then rounded up to the next multiple of five (51.2 miles would be rounded up to 55 miles), and a multiplier specific to the county designation is applied to determine the analogous maximum time criterion. We requested comment on our customization methodology and whether we should adjust factors in the distance calculation to achieve outcomes that are more equitable.

Customization of base criteria may be triggered based on information received through exception requests from plans, or from other sources, such as certificates of need (CON) from state departments of health. However, we proposed that CMS may only use customization to increase time and distance standards from the base standards, and may not reduce time and distance standards below the base standards. We solicited comment from the industry on other sources of information that CMS should consider and how it would work within the structure of our network adequacy standards.

Historically, we have required that at least 90 percent of the beneficiaries residing in a particular county have access to at least one provider/facility of each specialty type within the published maximum time and distance standards for that county. In an effort to encourage more

³⁷ CMS built the MA Medicare Sample Census, which derives from information maintained by CMS on the residence of Medicare beneficiaries. CMS built the Sample Census to be an adequate representative sample of Medicare beneficiaries in each applicable county. This file is only available to CMS and is only utilized for the purposes of measuring network adequacy.

MA offerings in rural areas, we proposed to reduce this percentage to 85 percent in Micro, Rural, and CEAC counties. In these generally “rural” counties, there is evidence of a lower supply of physicians, particularly specialists, compared to urban areas.³⁸ In order to account for this shortage, two state Medicaid programs that utilize network adequacy criteria have adjusted percentages in rural counties to require that standards be met for less than 100 percent of enrollees. New Jersey allows an 85 percent coverage requirement for primary care in “non-urban counties” but 90 percent in urban counties.³⁹ Tennessee’s Medicaid managed care program takes a slightly different approach, requiring that 60 percent of enrollees have access within 60 miles and 100 percent within 90 miles.⁴⁰ Additionally, the Part D program has a 90 percent retail pharmacy network coverage requirement in urban and suburban areas that drops to 70 percent for rural areas.⁴¹ Further, our data indicates that existing failures in MA plans’ meeting the time and distance standards frequently occur at the range between 80 to 89 percent of beneficiaries. As a result, we proposed to adopt a similar change in our MA network adequacy approach to account for access challenges in Micro, Rural, and CEAC counties; at § 422.116(d)(4)(i) we proposed that at least 85 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published time and distance standards in Micro, Rural, and CEAC counties. We estimated that approximately 14 percent of contracts (96 contracts) operating in these county designations will benefit from the reduced percentage and

³⁸ Department of Health and Human Services, National Advisory Committee on Rural Health and Human Services (2018) “Rural Health Insurance Market Challenges: Policy Brief and Recommendations.” Retrieved April 3, 2019, from: <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2018-Rural-Health-Insurance-Market-Challenges.pdf>

³⁹ State of New Jersey Dept of Human Services. “Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services and _____, Contractor” Sec. 4.8.8 “Provider Network Requirements” Retrieved April 5, 2019, from: <https://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf>

⁴⁰ State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Division of TennCare (2019) “Statewide Contract with Amendment 9 – January 1, 2019” Attachment IV. Retrieved April 3, 2019, from: <https://www.tn.gov/content/dam/tn/tenncare/documents/MCOStatewideContract.pdf>

⁴¹ Section 423.120(a)(1)

will no longer need to submit an exception request. We proposed to codify the existing policy of using a 90 percent threshold for Large Metro and Metro counties in § 422.116(d)(4)(ii). We noted that this specific proposal did not include a change from current policy requirements for a minimum number of provider specialties and facilities and that we proposed, at paragraph (e), that MA plans would still be required to maintain contracts with a minimum number of providers in each county.

We also proposed to give an MA plan a 10-percentage point credit towards the percentage of beneficiaries residing within the applicable time and distance standards for certain provider specialty types when the plan contracts with telehealth providers for those specified specialty types. For example, in a rural county where an MA plan must have 85 percent of beneficiaries residing within applicable time and distance standards, the MA plan would receive an additional 10 percentage points towards the 85 percent requirement should they contract with applicable telehealth providers under § 422.135. We explained that this is not currently part of the network adequacy evaluation, but we believed it is appropriate in light of the expanding coverage in the MA program of additional telehealth benefits. In the April 2019 final rule, we adopted § 422.135 to implement the option for MA plans to offer additional telehealth benefits as part of their coverage of basic benefits under section 1852(m) of the Act, as amended by section 50323 of the BBA of 2018. In that rulemaking, we solicited feedback from the industry concerning the impact, if any, that telehealth should have on network adequacy policies. We received approximately 35 responses from stakeholders in managed care, provider, advocacy, and government sectors. While health plans clearly favored taking into account telehealth access while evaluating network adequacy, providers had more concerns that telehealth services could be used to replace, rather than supplement, in-person healthcare delivery. A commenter stated

that it is imperative that beneficiaries continue to have the choice to access services in-person not only as a matter of preference, but to ensure those that do not have access to the required technologies are not left without care. Section 1852(m)(4) of the Act and the regulation at §422.135(c)(1) require that an enrollee in an MA plan offering additional telehealth benefits must retain the choice of receiving health care services in person rather than through electronic exchange (that is, as telehealth). With that in mind, and emphasizing the importance of maintaining an in-person network, we did not propose any changes to how we currently calculate minimum provider requirements and MA plans would still contract with a minimum number of providers for each specialty type. We explained that we believed this is imperative for MA plans to be able to provide in-person care when needed or when preferred by the beneficiary and that contracting with telehealth providers as a supplement to an existing in-person contracted network would give enrollees more choices in how they receive health care. Further, we explained that it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, their in-person networks with telehealth providers. We proposed, at § 422.116(d)(5) to provide a 10-percentage point credit towards the percentage of beneficiaries residing within time and distance standards for specific provider specialty types by county when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Since additional telehealth benefits described at § 422.135 only apply to MA plans, cost plans would not be eligible for this 10-percentage point credit under proposed § 417.416(e)(3).

We explained that a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage score because telehealth providers add value to

a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, we noted how information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80 to 89 percent range. Therefore, we stated, a 10-percentage point credit is significant enough to have an impact on MA plans and encourage the use of telehealth, while being proportionate to the role that telehealth providers have in a contracted network. Further, we proposed to apply this telehealth credit only to five specific provider specialty types: dermatology, psychiatry, neurology, otolaryngology and cardiology. We explained that this limited approach would allow CMS to monitor the effectiveness of the credit, while also allowing us to determine whether there may be access or quality of care impacts. As we discussed in the April 2019 final rule, additional telehealth benefits are monitored by CMS through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations will alert CMS to any issues with access to care and CMS may require MA organizations to address these matters if they arise.

We explained how we identified the five provider types for this proposal. CMS considered previous input from industry stakeholders, publicly available studies, and analyses of Medicare claims data for telehealth services in determining applicable provider specialty types. We considered not only the potential that telehealth has within a specialty type, but also the observed access challenges for provider specialty types over the years of our network adequacy reviews. In our experience, most MA plans do not have challenges meeting time and distance standards for primary care as compared to non-primary care provider specialty types. We also stated that it is critical to quality health care that Medicare beneficiaries have a primary care provider that they can visit in person and within a suitable time and distance. Therefore, despite

the potential and prevalence of telehealth for furnishing primary care services, we did not believe that it was necessary to take telehealth access into account when measuring and setting minimum standards for access to primary care providers. We solicited comments on the provider specialty types we proposed to be eligible for the telehealth credit and whether CMS should expand or limit this credit to a different set of provider specialties.

In the proposed rule, we explained that we had received comments from providers and physician groups about the limitations of current network adequacy policies on dialysis treatment when performed in a hospital, at home, or in an outpatient facility. Some research suggested that home-based dialysis may offer advantages over in-center hemodialysis, including patient convenience, reduction in costs associated with dialysis, and potentially improved patient quality of life and blood pressure control with greater survival and fewer hospitalizations.⁴² We acknowledged in the proposed rule that there is more than one way to access medically necessary dialysis care and stated that we wanted plans to exercise all of their options to best meet a beneficiary's health care needs. We solicited comment on: (1) whether CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring each MA plan to meet time and distance standards for providers of these services; (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities.

⁴² Comparative Effectiveness of Home-Based Kidney Dialysis Versus In-Center or Other Outpatient Kidney Dialysis Locations – A Systematic Review [Internet]: <https://www.ncbi.nlm.nih.gov/books/NBK344417/>

Additionally, we explained that CMS had received comments concerning patterns of provider consolidation and its impact on higher costs for patients. We received feedback from stakeholders that providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare FFS rates. We solicited comment on existing problems and behavior in non-rural, consolidated provider markets and recommendations that we could take to encourage more competition in these markets.

We also proposed a policy to incorporate consideration of Certificate of Need (“CON”) laws into our network evaluations, as a modification from our current policy after a brief summary of the topic. President Trump’s Executive Order 13890 on Protecting and Improving Medicare for Our Nation’s Seniors (October 3, 2019) calls for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain CON laws or other anticompetitive restrictions. Many states began adopting CON laws in the 1960s and 1970s in part to promote resource savings and to prevent investments that could raise hospital costs.⁴³ A number of studies have found no evidence that CON programs have led to resource savings, and in some instances, may raise health care costs. In one study published in 2013, researchers studied whether states that dropped CON programs experienced changes in costs or reimbursements from coronary artery bypass graft surgery or percutaneous coronary interventions.⁴⁴ In this study, the cost savings from removing the CON requirements slightly exceeded the total fixed costs of new facilities that entered after deregulation. Another study published in 2016 concluded that there is no evidence that CON requirements limit health care price inflation and little evidence that they

⁴³ Daniel Sherman, “The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis,” *Federal Trade Commission*, January 1988.

⁴⁴ Vivian Ho, Meei-Hsiang Ku-Goto, “State Deregulation and Medicare Costs for Acute Cardiac Care,” *Med Care Res Rev.*, April 2013.

reduce health care spending.⁴⁵ It further concluded that CON laws are associated with higher per unit costs and higher total healthcare spending. Most relevant here, other studies suggest that the removal of these laws that serve as a barrier to entry into the market lead to greater access to providers and a redistribution of health care services to higher quality providers, improving the overall quality of health outcomes.⁴⁶

After listing this research, we stated that it pointed out that CON laws restrict the supply and competition for healthcare services and increases costs and that CON laws adversely affect access in states and counties where they are in effect, including for MA organizations that operate in those areas. CMS pays MA organizations a capitated amount in each county for the provision of Medicare benefits based on the expected costs to provide benefits. When MA organizations must pay more for benefits, as the research demonstrates happens when there are fewer providers or facilities with which to contract, that reduces the access to benefits offered by MA organizations. In order to take into account the adverse effects that CON laws have on access, we proposed in § 422.116(d)(6) to provide that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anticompetitive restrictions, that limit the number of providers or facilities in a county or state. In the proposed rule, we explained that, where appropriate, CMS may instead address network adequacy by customizing base time and distance standards in states with CON laws. We explained that the proposal was justified based on the studies cited that have shown that CON laws adversely affect competition and free market entry in states and that our network

⁴⁵ Matthew D. Mitchell, “Do Certificate-of-Need Laws Limit Spending?” *Mercatus Working Paper*, Mercatus Center at George Mason University, Arlington, VA, September 2016.

⁴⁶ David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, “Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery,” *American Economic Journal: Economic Policy*, February 2010.

adequacy policy thus should provide for us to consider this factor when evaluating the adequacy of an MA organization's contracted network.

We proposed to make this credit equal to and in addition to, if applicable, the proposed telehealth credit (10 percentage points) for reasons similar to those for the telehealth credit policy: information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80 to 89 percent range. We explained that, under our proposal, CMS could elect to grant this credit instead of customizing time and distance standards depending on a number of factors, like the speed of implementing customized standards, operational and timing constraints, and the amount of work required to calculate customized time and distance standards. We solicited comment on additional criteria or factors we should consider when deciding whether to apply the 10-percentage point credit or customize time and distance standards in the impacted states or counties. Additionally, we solicited comment about what other actions CMS could take in markets with state CON laws.

We also considered whether there are circumstances where a more limited application of network adequacy flexibility might be more appropriate. We solicited comment as to how and under what circumstances we should refrain from applying the 10 percentage point credit, should mitigate the size of this credit, or other actions we might undertake to apply this flexibility in a more limited manner.

5. Minimum Number Standards

We proposed to codify the current policy that MA plans must contract with a specified minimum number of each provider and facility specialty type in § 422.116(e). The MA plan must have a minimum number of in-person providers and facilities in each county for each specialty type specified in paragraph (b). We explained the general rules at § 422.116(e)(1) that

the provider or facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirement and cannot be a telehealth-only provider. We also proposed to codify the methodology for establishing the minimum number requirements for specific contracted provider and facility specialty types per county. We explained that CMS would use this methodology each year to determine and publish the updated minimum provider standards on an annual basis and that certain standards for the minimum number of providers are updated annually to account for changes in the Medicare population, MA market penetration, and county designations. Our proposal required the provider/facility to be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirements. We noted that the location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards.

We proposed to codify at § 422.116(e)(2)(iii), our existing practice that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. We limited the methodology for establishing and changing the required minimum number standard to acute inpatient hospitals and other non-facility provider specialties. We proposed the methodology at §422.116(e)(3): CMS determines the minimum number requirement for all provider specialty types and Acute Inpatient Hospitals by multiplying the “minimum ratio” by the “number of beneficiaries required to cover,” dividing the resulting product by 1,000, and rounding up to the next whole number. The steps and components of the methodology were proposed in paragraphs (e)(3)(i) and (ii) and explained in the preamble of the proposed rule.

The Minimum Ratio is the number of providers required per 1,000 beneficiaries, and for Acute Inpatient Hospitals, the number of beds per 1,000 beneficiaries. We stated that CMS had

established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We proposed to codify those minimum ratios in the regulation at § 422.116(e)(3)(i) and reproduced it in the preamble as Table 13. (85 FR 9101)

We stated that the Number of Beneficiaries Required to Cover is also calculated by CMS based on an established methodology. The Number of Beneficiaries Required to Cover is the minimum population that an MA plan's network should be able to serve and represents the potential number of beneficiaries an organization may serve within a county. We proposed at § 422.116(e)(3)(ii)(A) that the Number of Beneficiaries Required to Cover is calculated by multiplying the "95th Percentile Base Population Ratio" times the total number of Medicare beneficiaries residing in a county. We explained that CMS uses its MA State/County Penetration data to calculate the total number of Medicare beneficiaries residing in a county. For counties with lower populations, and particularly for specialties with lower minimum ratios, the minimum number is usually one.

We proposed to continue the current policy of calculating the 95th Percentile Base Population Ratio annually for each county type. We explained in the proposed rule that CMS has previously allowed MA organizations to provide their expected enrollment and then define their networks based on that number, but had later developed and implemented a more objective means to measure network adequacy for all MA plans consistently. Based on our position that the 95th Percentile Base Population Ratio is a fair and consistent enrollment estimate that can be applied to new and current plans, we proposed to codify its continued use. While it varies over

time as MA market penetration and plan enrollment changes across markets, the 95th Percentile Base Population Ratio currently ranges between 0.073 and 0.145 depending on county type, indicating that MA plans are expected to have networks at least sufficient to cover between 7.3 percent (Large Metro) and 14.5 percent (CEAC) of the Medicare beneficiaries in the county. This ratio represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level). We explained in the proposed rule how to calculate the 95th Percentile Base Population Ratio. We use the List of PFFS Network Counties⁴⁷ to exclude PFFS plans in non-networked counties⁴⁸ from the calculation at the county type level. We use the MA State/County Penetration data⁴⁹ to determine the number of eligible Medicare beneficiaries in each county, and our Monthly MA Enrollment data⁵⁰ to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types. We calculate penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county. Finally, we group counties by county designation to determine the 95th percentile of penetration among MA plans for each county type. We proposed to codify the methodology for calculating the 95th Percentile Base Population Ratio at § 422.116(e)(3)(ii)(B).

6. Exceptions

⁴⁷ CMS. PFFS Plan Network Requirements. Retrieved from: <https://www.cms.gov/Medicare/Health-Plans/PrivateFeeForServicePlans/NetworkRequirements.html>

⁴⁸ Non-networked counties in this context means there are not at least two networked plans operating in that county.

⁴⁹ CMS. MA State/County Penetration. Retrieved from: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/MA-State-County-Penetration.html>

⁵⁰ CMS. Monthly MA Enrollment by State/County/Contract. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/Monthly-MA-Enrollment-by-State-County-Contract.html>

Finally, we also proposed to codify in paragraph (f) a process by which an MA plan may request and receive an exception from the network adequacy standards in § 422.116. Under our current policy, CMS conducts network adequacy reviews through an automated process, but also allows for exceptions to that process when failures are detected in the submitted network. We proposed to codify the exceptions process, the basis upon which an MA plan may request an exception, and the factors that CMS may consider when evaluating an MA organization's request for an exception to the standards in § 422.116. We proposed that an MA organization may request an exception when two criteria are met: (1) certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type, and (2) the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. For example, certain providers/facilities may not be available for contracting when the provider has moved or retired, or when the provider/facility does not contract with any organizations or exclusively with another organization. We proposed that we would implement and interpret the regulation such that the MA plan would have to contract with telehealth providers, mobile providers, or providers outside the time and distance standards, but accessible to most enrollees (or consistent with the local pattern of care), in order for the MA plan to request an exception by CMS. In evaluating exception requests, CMS proposed that it would consider: (i) whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; (ii) whether there are other factors present, in accordance with §422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of

care; and (iii) whether approval of the exception is in the best interests of beneficiaries. These three criteria were proposed to be codified at paragraph (f)(2)(i), (ii) and (iii).

Currently, CMS collects information for purposes of testing an MA organization's network adequacy using the PRA-approved collection titled, "Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans, CMS-10636, OMB 0938-1346."⁵¹ CMS relies on this collection of information to evaluate whether an MA organization maintains a network of appropriate providers and facilities that is sufficient to provide adequate access to covered services based on the needs of the population served. In the PRA package, CMS explained that organizations must comply with the current CMS network adequacy criteria posted in the HSD reference file on CMS's website and updated annually. We proposed to codify the standards in order to formalize the use of criteria posted in the HSD reference file by codifying and explaining the standards and, where necessary, the formulas used to calculate network adequacy standards (that is, provider/facility types, maximum time and distance standards, minimum provider/facility numbers). We proposed that CMS would continue to use the HSD reference file as a means to communicate these standards to MA organizations and that we anticipated that there would be no updates or changes required to the approved collection of information for CMS to assess network adequacy. We stated in the proposed rule how the codified provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. We confirm here that these provisions are not subject to the PRA.

We thank commenters for their input to help inform our final rule on network adequacy policies. We received the following comments on this proposal, and our response follows:

⁵¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10636>

Comment: A number of commenters gave feedback regarding the provider and facility specialty type lists in § 422.116(b). Some commenters suggested that CMS add provider specialty types for physical therapist, occupational therapist, transplant providers, psychologists, clinical social workers, nurse specialists, emergency physicians, and optometry. A few commenters suggested that CMS add transplant centers and inpatient rehabilitation hospitals and units to the list of facility specialty types.

Response: We appreciate the many viewpoints and recommendations on this subject. The regulation at § 422.112(a) require that MA organizations must ensure that all covered services are available and accessible under the plan. Further, MA organizations must maintain a network of providers to provide adequate access to covered services and must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable. As a result of this critical protection, we do not require that all provider and facility specialties be subject to network adequacy standards. In past network adequacy reviews, we have not evaluated every possible provider type that may provide a Medicare covered benefit in our network reviews. We also have not evaluated provider subspecialties, especially those that are extremely specialized in nature. We ensure access to all Medicare covered services through monitoring and investigating complaints in the CMS Complaint Tracking Module. We identify which provider and facility specialty types are critical and necessary to evaluate separately based on a review of Medicare FFS utilization patterns, utilization of provider/facility specialty types in Medicare FFS, specialties in other managed care programs, and the clinical needs of Medicare beneficiaries. For example, we consider the utilization rate of specific provider types in order to determine if it justifies the effort of developing specific standards, collecting data from plans, and analyzing the information.

Therefore, we proposed to codify network adequacy standards for the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area and have well-established base time and distance standard associated with them. We emphasize that MA enrollees are entitled to access to all medically necessary services from Medicare participating providers and facilities whether or not the provider or facility type is subject to specific network adequacy standards under § 422.116.

Comment: In response to our identification of other options we were considering regarding outpatient dialysis centers, many commenters supported removing outpatient dialysis from the list of facility specialty types, and instead, requiring an attestation in its contract application. These commenters explained that this change would drive patient-centered innovation in dialysis treatment, encourage competition, and bring down high reimbursement costs for dialysis treatment. They also pointed out that this change would be consistent with how CMS monitors and ensures beneficiary access to durable medical equipment, home health care, and transplant services. Commenters suggested that the use of an attestation would ensure patient protection while also giving plans the flexibility they need to expand the delivery of innovative solutions to beneficiaries with End Stage Renal Disease (ESRD) requiring dialysis treatment. A few commenters that supported the removal of outpatient dialysis also suggested that providing exceptions for plans covering home dialysis for all beneficiaries who need such services or customizing time and distance standards for dialysis facilities would also improve the proposal.

On the other hand, many commenters recommended that CMS finalize its proposal and maintain maximum time and distance standards for outpatient dialysis centers without change. These commenters raised concerns that the removal of outpatient dialysis as a facility type would

result in the discrimination of ESRD patients by MA plans because the network design would discourage patients with ESRD from enrolling. A few commenters believed that the removal of outpatient dialysis centers from the list of facility and specialty types for which we would use specific standards would conflict with the intent of the 21st Century Cures Act, which allows ESRD patients to enroll in MA plans in 2021. Some commenters raised access to care concerns and pointed out barriers to home dialysis, such as housing insecurity and a lack of caregiver support, and others explained the need to have both home dialysis and in-center dialysis options of care and to leave the treatment choice in the hands of the patient. Lastly, a couple commenters did not believe that CMS provided adequate notice in the proposed rule to make any changes to outpatient dialysis in the final rule.

Response: In our proposal, we explained that we believed that there is more than one way to access medically necessary dialysis care and we sought to improve our network adequacy standards as they relate to measuring and setting minimum standards for access to dialysis services. We do not agree with commenters that the removal of outpatient dialysis facilities will result in network designs that discriminate against or discourage ESRD beneficiaries from enrolling in MA plans. Regardless of whether a facility or provider specialty type is subject to network adequacy standards, MA organizations are required in § 422.112(a)(3) to arrange for health care services outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Section 422.112(a)(10) requires MA plans to ensure access and availability to covered services consistent with the prevailing community pattern of health care delivery in the areas served by the network. The factors making up community patterns of health care delivery that CMS considers when evaluating an MA plan network – and which continue to apply regardless whether a specific time and distance or

minimum number requirement is established pursuant to § 422.116 for a provider specialty or facility type – are at § 422.112(a)(10). For example, for any provider or facility types that are not included in network adequacy standards at § 422.116, CMS may consider the number and geographical distribution of eligible health care providers available to potentially contract with an MA organization to furnish plan covered services within the service area when deciding if MA plans meet access and availability requirements. Additionally, we may consider the prevailing market conditions in the service area of the MA plan and, more specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan. Therefore, if network providers are incapable of meeting the enrollee’s medical needs because the burden of travel to the in-network dialysis center is inconsistent with the prevailing community pattern of health care delivery in the area, the MA plan must arrange for care outside of the network and at in-network cost-sharing in order to meet the MA plan’s obligation under the MA program rules to furnish covered services. The network adequacy maximum time and distance standards proposed at § 422.116 are one way that we quantify prevailing patterns of health care delivery in areas, but it is not the only way to evaluate a network, as § 422.112(a)(10) provides. Most importantly, it does not mean that MA organizations do not need to maintain an adequate contracted network of contracted providers simply because a provider or facility type is not included in the network adequacy standards at § 422.116. MA organizations must maintain a network of contracted providers that is sufficient to provide adequate access to covered services to meet the needs of the population served and is consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. This critical beneficiary protection ensures that MA enrollees have similar reasonable access to providers and

facilities as beneficiaries in FFS Medicare. Therefore, we believe that MA plans will continue to provide adequate access to dialysis providers. We disagree with commenters that believe that the removal of outpatient dialysis from the list being finalized in § 422.116 of facility types that are separately evaluated on time and distance and minimum number standards would necessarily lead to discrimination against ESRD patients or would conflict with the intent of the 21st Century Cures Act. The 21st Century Cures Act removed the prohibition against beneficiaries with ESRD from enrolling in an MA plan effective for plan years beginning on or after January 1, 2021. MA organizations must abide by all existing legal and regulatory anti-discrimination requirements, which include prohibitions on discrimination on the basis of health status, for any beneficiaries with ESRD enrolling in an MA plan.

For CMS performance data collected for Part C Star Ratings, CMS surveys beneficiaries on the ease of getting needed care and seeing specialists, as well as getting appointments and care quickly, through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey questions. MA organizations are incentivized by CMS Star Ratings policies to maintain high-star ratings by scoring well on these types of survey measures. Further, if beneficiaries believe that an MA organization is discriminating against them, complaints may be submitted into the Complaint Tracking Module (CTM). We monitor and investigate complaints related to access concerns and work with regional office caseworkers to resolve any issues with the MA organizations. We would take compliance or enforcement actions against an MA organization for failing to provide adequate access to medically necessary services, as warranted.

Also, we do not believe that the removal of outpatient dialysis as a facility type would cause access to care concerns. As we pointed out, MA organizations must maintain a contracted network that is sufficient to provide adequate access to covered services, and this includes the

ability for enrollees to receive care in-person at an outpatient dialysis facility. We agree with commenters that this change will drive patient-centered treatment in dialysis services, which is at the heart of our intent in considering this change in policy. While we proposed to codify maximum time and distance standards for the facility type outpatient dialysis, we also solicited comments about four options to improve measuring and setting standards for access to dialysis services because we wanted MA plans to use more than one treatment modality to address access to dialysis services: (1) removing outpatient dialysis from the list of facility types with specific evaluation standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services); (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities. We believe that by eliminating the outpatient dialysis facility type from the list in § 422.116(b)(2), MA organizations have the freedom to enhance their networks by contracting with dialysis providers that offer dialysis treatment through home-based modalities. These home based modalities give enrollees flexibility and control over their lives so that enrollees can choose the treatments that best meet their needs. We agree with commenters and understand that beneficiaries undergoing dialysis treatment often face changes in circumstances that may warrant movement from one modality to another. We believe this further supports our intent to encourage MA organizations to establish networks that provide the most advanced and available treatment options to Medicare beneficiaries.

We also agree with commenters that the removal of outpatient dialysis from the list of facilities for which there are specific time and distance and minimum provider standards could encourage greater competition in dialysis treatment and treatment modalities, which will

eventually lead to lower costs for Medicare beneficiaries without resulting in the denial of, or access to, lesser care. The removal of outpatient dialysis as a facility type from our network adequacy standards allows all dialysis treatments to be treated equally, which will encourage MA organizations to contract with facilities that offer different forms of dialysis treatments, rather than just dialysis at an outpatient facility. We believe this increased competition among treatment modalities could drive down plan and patient costs for dialysis services. We do not believe that creating exceptions related to home dialysis or customizing time and distance standards will bring about the same level of change that CMS is seeking. CMS will continue to oversee the provision of dialysis services through its monitoring efforts to ensure that MA beneficiaries have access to medically necessary care that meets their needs. We routinely monitor access to care complaints and impose compliance or enforcement actions, when necessary, to hold MA organizations accountable for the provision of all medically necessary covered services.

Lastly, a few commenters did not believe that CMS provided adequate notice and sufficient detail in the proposed rule for the alternative that we are finalizing here. We disagree and believe that our proposal and continued consideration of other options for outpatient dialysis were clear in the proposed rule. We received numerous comments discussing the four options we identified in the proposed rule (85 FR 9099), as well as the proposal to include outpatient dialysis as a facility type with maximum time and distance standards. The comments, as we have previously discussed, weighed these options and clearly discussed the benefits and drawbacks on the merits of the issues presented, indicating to us that our consideration of other options for outpatient dialysis was understood by commenters. We thank commenters for all of their input in helping to inform us as we considered a final policy concerning outpatient dialysis.

In this final rule, we are removing outpatient dialysis as a facility specialty type at § 422.116(b)(2) that is subject to network adequacy standards. Under our authority in § 422.116(a)(1), we intend to require that MA organizations submit an attestation that it has an adequate network that provides the required access and availability to dialysis services, including outpatient facilities. We are finalizing the 27 provider specialty types and the other 13 facility types (that is, the types other than outpatient dialysis facilities) in § 422.116(b) as proposed.

Comment: A few comments questioned our proposal at § 422.116(b)(3) specifying that CMS may remove a provider or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. A few commenters recommended that both additions and removals of provider and facility types be subject to notice and comment rulemaking.

Response: The HSD reference file is built annually by applying the rules in § 422.116. We reiterate the importance of the beneficiary protection at § 422.112(a), that even if a provider or facility specialty type is not subject to network adequacy standards, that access to providers at in-network cost-sharing must be provided by the MA organization. We proposed the ability to remove specialty types in the HSD reference file to account for circumstances where it may not be necessary to evaluate the number and accessibility of each of the 27 specialty and 13 facility types in a particular year. Additionally, as we described in our proposal, § 422.116(a) will permit us to require an MA plan to complete an attestation that it has an adequate network that provides the required access to and availability of provider or facility specialty types even where we do not evaluate access ourselves. Since network adequacy criteria are measured for each individual specialty type and do not roll up into an aggregate score, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and,

as discussed throughout this section of this final rule, we believe that there are adequate protections available to ensure that enrollee access to services is not compromised. We are finalizing § 422.116(b)(3) to allow CMS to remove a provider or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

Comment: Most commenters supported the proposed base time and distance standards. There were a few commenters that suggested that CMS consider alternative approaches to codifying a uniformly applied time and distance standard. A commenter suggested that CMS allow for the use of a combination of qualitative and quantitative standards. Others commenters suggested measures of provider availability (for example, percentage accepting new patients, timeliness of appointment availability), performance on access-related quality and patient experience measures, and degree of physical co-location of services.

Response: We appreciate the recommendations and, because we are always looking for new ways of improving the network adequacy reviews, will take them into consideration for potential future policy development. Our network adequacy methodology, as proposed and as finalized here, aims to objectively evaluate the networks of various types of coordinated care plans across a national landscape that includes urban, suburban, and rural regions. We believe that using quantitative methods that account for some degree of variance across these different regions provides a fair and reasonable evaluation that we can efficiently test against hundreds of MA plans annually. Therefore, we are finalizing base time and distance standards that vary by county type designation and take into account the nature of the provider or facility supply in the health care marketplace. Further, the customization process, which we are finalizing as proposed at paragraph § 422.116(d)(3), allows us to adjust the base time and distance standards, when

needed, to take into account the unique characteristics of specific regions, such as geographic landscape, which may alter the pattern of care in a county. We also proposed an exceptions process at § 422.116(f), which allows us to also consider qualitative characteristics that may serve as the rationale for a valid exception when an MA network fails to meet time and distance standards. We have continued to hone and improve our network adequacy methodology since 2011 and believe our objective and transparent approach allows for the proper balance of quantitative and qualitative measures that allows CMS to quickly and efficiently measure the adequacy of hundreds of MA networks in a given year. We also note that some of the performance measures (for example, patient experience and access-related quality measures) suggested are already included in CMS's MA plan Star Ratings system, which is used to measure how well plans perform in several categories, including quality of care and customer service. We do not believe it is necessary to duplicate those as part of network evaluations.

Therefore, we are finalizing the general rules for network adequacy proposed at § 422.116(a), with the exception of § 422.116(a)(3)(ii), which will not be finalized to align with how we are not finalizing specific standards for Outpatient Dialysis facilities. Also, we are finalizing the county type designations at § 422.116(c) and the maximum time and distance standards at § 422.116(d) as proposed, with the exception of the maximum time and distance standards for the Outpatient Dialysis facility type for reasons previously discussed.

Comment: A number of commenters supported the proposed base time and distance standards at § 422.116(d). A few commenters recommended changes to the proposed base time and distance standards in specific county type designations or due to the plan type. Some commenters recommended that Institutional Special Needs Plans (I-SNPs) should have reduced network adequacy standards for specific provider or facility types like podiatry, primary care,

diagnostic radiology, physical therapy, occupational therapy, and speech therapy, or should be excepted altogether from the measures. Others recommended that we reduce time and distance standards for occupational therapy and dermatology in all county types, and for primary care and psychiatry in non-metro county types.

Response: We conduct network adequacy reviews at the contract level, meaning we evaluate the adequacy of the MA organization's network across all of their plan types (for example, HMOs, PPOs, SNPs); we do not singularly evaluate the network of a specific plan benefit package. We believe that conducting network reviews at the contract level allows us to consider the broadest availability of contracted providers and facilities for an MA organization while also providing administrative efficiency for CMS to evaluate fewer HSD network submissions. Therefore, our network methodology does not change base time and distance standards based on the plan type being reviewed, such as an I-SNP. We also do not believe that it would be necessary to change our network adequacy standards based on the plan types that we review. For example, while I-SNPs may be unique in that beneficiaries may receive a number of health care services from a single institution, there are also I-SNP institutionalized-equivalent beneficiaries that reside at home. Further, these beneficiaries may still need to travel to another facility to receive specialized care or the specialty providers will need to travel to deliver the care. As a result, we believe that even for plans like I-SNPs, it is important that MA organizations maintain a contracted network that can deliver medically necessary care and is compliant with our network adequacy standards.

We have honed and improved its base time and distance standards for each specific provider and facility type in each county designation over a period of nine years. For example, we updated maximum time and distance standards when the new county designation

methodology was implemented (that is, moving from classifying counties based on metropolitan statistical areas to the current county designations) and have adjusted some standards based on a significant change in supply. We proposed base time and distance standards that we believe represent a fair expectation for health care patterns of delivery in the five county types based on many years of data and network evaluation. Additionally, the customization process, as proposed and finalized, allows us to adjust standards at the county and provider/facility type level where needed to take into account factors like utilization or supply patterns that indicate the base time and distance standards are not reflective of prevailing patterns of community health care delivery. Therefore, we are not making any changes to our base time and distance standards in the final rule and are finalizing these standards as proposed.

Comment: A number of commenters supported the minimum provider number requirements at § 422.116(e). Commenters supported CMS's policy that there be at least one contracted provider or facility specialty type within required time and distance standards that is accessible to Medicare beneficiaries. A commenter recommended that CMS use the same minimum provider ratio in the calculation of the minimum provider number requirement in all county types.

Response: We thank commenters for their support of this policy. As we described in our proposed rule, CMS established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We proposed Minimum Ratios for each provider and county type at § 422.116(e)(3)(i). The Minimum Ratio is the number of providers required per 1,000

beneficiaries. As the overall population and population density widely varies between large metro and rural county types, so does the rate of health care utilization in these areas. Health care utilization patterns are higher in metro areas, and therefore, our proposed Minimum Ratios are slightly higher in metro county types. In accordance with our current rules at § 422.112(a)(10), we considered the prevailing patterns of community health care delivery, such as whether the service area is comprised of rural or urban areas, when developing the Minimum Ratios. We are finalizing the minimum number requirements as proposed in § 422.116(e).

Comment: Many commenters supported our proposed customization process at § 422.116(d)(3). In particular, commenters supported that CMS may only use customization to increase time and distance standards from the base standards. A commenter suggested that CMS allow health plans to provide feedback on county time and distance standard changes to ensure appropriate customization is consistent year after year. Other commenters suggested that geographic barriers like rivers, mountains, and oceans should trigger customization, in addition to supply shortages.

Response: We appreciate commenters' support of our customization process. We agree with commenters that geographic barriers that play a significant role in utilization patterns are triggering events that may result in the customization of time and distance standards by CMS. We clarify here, and in additional regulation text being finalized at § 422.116(d)(3), that when necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for specific provider or facility types for specific counties by customization. We stated in the proposed rule that customization of base criteria may be triggered based on provider or facility supply shortages, information received through exception requests from plans, or from other sources, such as restrictions or limitations caused by state certificate of need (CON) laws.

When information from these sources shows that utilization or supply patterns indicate the base time and distance standards are not reflective of prevailing patterns of community health care delivery, CMS may customize the maximum time and distance standards. In the past, CMS has only customized maximum time and distance standards by increasing them above the base time and distance standard and will continue this policy by finalizing § 422.116(d)(iv). We solicited comment in the proposed rule about other sources of information that we should consider as part of the customization analysis, but we do not believe that it is necessary or appropriate to limit the source or type of information that could be used to trigger the customization analysis. By codifying a standard to guide when we will use customization without limiting the information that would indicate that utilization or supply standards make it necessary to use customized, instead of the base, time and distance standards, we are ensuring that the network adequacy evaluations appropriately reflect access and availability of health care for each area.

Customization of base time and distance standards occurs narrowly and is very specific to the provider or facility specialty type and county where the triggering event occurs. Further, MA organizations will not be subject to reductions in the time and distance standard below the base standards at § 422.116(d)(2); CMS will only be increasing from the base standards through customization to take into account the information and utilization and supply standards that trigger the need for customization and make it easier for MA organizations to comply with network adequacy standards. As such and because the regulation describes the standards governing the customization process, we do not believe an opportunity for prior review and comment on customized time and distance standards before implementation is the best course of action. As we mentioned, we consider information from exception requests to help inform our customization of time and distance standards. Should an MA organization continue to fail to

meet customized time and distance standards, the organization may submit an exception request and provide further information about why its network cannot meet the standard. CMS will take that information under consideration for the current network review and may make additional adjustments to the customized time and distance standards in the following year. We believe this is the most efficient means of receiving MA organization input on customized standards as circumstances in counties change year over year. Therefore, we are finalizing the customization process at § 422.116(d)(3), with an addition to clarify that CMS may set maximum time and distance standards for provider or facility types for specific counties when necessary due to utilization or supply patterns.

Comment: We received numerous comments expressing support for the reduction in the percentage of beneficiaries residing within maximum time and distance standards in Micro, Rural, and CEAC counties from 90 percent to 85 percent. Some commenters described this as a reasonable adjustment in light of the limited availability of some providers in rural areas. They explained that this proposal could increase access to MA plans for beneficiaries residing in rural areas by bringing competition and better health care choices to beneficiaries. Other commenters that were supportive of the proposal also requested that CMS make this reduction applicable to all five county type designations, rather than limiting it to Micro, Rural, and CEAC counties. A few commenters suggested that we further reduce the percentage down to 80 percent.

We also received some comments that expressed opposition to this reduction. Some commenters expressed concern that reducing the threshold requirement may result in the unintended consequence of leaving some rural communities without appropriate access to essential services because it would reduce the incentives for MA plans to contract with specialists.

Response: We thank commenters for their viewpoints on our proposal to reduce the percentage of beneficiaries residing within maximum time and distance to 85 percent at § 422.116(d)(4)(i). We agree that a reduction is necessary in rural counties (Micro, Rural, and CEAC) due to the limited availability of providers and the lower population density in those areas. CMS considers the number and geographical distribution of eligible providers available to potentially contract with an MA organization when evaluating a network based on community patterns of care under § 422.112. The beneficiary population is typically less dense per square mile than in metro counties so we believe having a reduced threshold will make the standards more consistent with the community patterns of care in rural areas. As a result, we agree with commenters that this adjustment may increase access to MA plans for beneficiaries residing in rural areas. We do not believe that this reduction will result in leaving some rural communities without appropriate access to essential services. Our minimum number requirements proposed at § 422.116(e) require that an MA plan contract with at least one provider within maximum time and distance standards of a beneficiary in the area. Further, CMS rules at § 422.112(a) require that MA organizations must ensure that all covered services are available and accessible under the plan, regardless of how many providers or facilities are contracted with the MA organization. MA organizations must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable or the network is insufficient. Therefore, beneficiaries in these rural communities will continue to have access to specialty providers and facilities because MA organizations are still required to contract with at least one or must pay for health care services rendered at non-contracted Medicare participating providers at the Medicare FFS rate.

We proposed a modest reduction of 5 percent and limited this reduction to only Micro, Rural, and CEAC counties. We believe this to be an appropriate adjustment based on our data that shows that existing failures in MA plans' meeting the time and distance standards frequently occur at the range between 80 to 89 percent of beneficiaries. We understand that some commenters would like CMS to see an increased reduction or expand this reduction to all county types, however, we believe that the approach we are finalizing will allow us to observe the impacts of this policy change on MA plans and health care providers; we may consider further adjustments to the percentage as needed. Additionally, as this policy change was also intended to drive more MA plan access in rural areas, we do not believe it is necessary or appropriate at this time to apply this reduction to the access standard for metro counties. We are finalizing the reduction in the percentage of beneficiaries residing within maximum time and distance to 85 percent for Micro, Rural, and CEAC counties at § 422.116(d)(4)(i).

Comment: We received numerous comments about the 10-percentage point telehealth credit towards the percentage of beneficiaries residing within published time and distance standards for applicable provider specialty types proposed at § 422.116(d)(5). Most commenters were very supportive and appreciated CMS' support of telehealth goals and thought that CMS's proposal would incentivize MA organizations to contract with providers that have adopted telehealth technology. A few commenters were opposed to this "telehealth credit" and felt that telehealth should be implemented into network adequacy in a way that does not diminish access to in-person care. These commenters believed that allowing a telehealth credit would make it too easy for MA organizations to comply with a standard that is set for in-person access to a provider. Also, opposing commenters believed that this policy may unintentionally encourage

plans to use telehealth services as substitutes for existing in-person services, even in areas where provider availability and beneficiary access are strong.

Response: We appreciate commenters support for this proposal as well as the concerns that were raised by the commenters that opposed it. We believe the telehealth credit that we proposed upholds maximum time and distance standards for the applicable provider specialty types and provides a modest incentive for MA organizations to supplement their networks with providers that can furnish additional telehealth benefits. Our proposal does not decrease the maximum time and distance standards that must be maintained for compliance with our network adequacy measures for the applicable provider types; it allows for a reduced portion of the beneficiary population to be within those maximum time and distance standards. For example, in Metro counties, MA organizations would still need to ensure that they contract with in-person providers that are within maximum time and distance standards of at least 80 percent of the beneficiary population even after the credit is applied. We believe it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, in-person networks with telehealth providers. The rules at § 422.135(c) for providing additional telehealth benefits require that the MA organizations furnish in-person access to the specified Part B service at the election of the enrollee. This protection preserves the beneficiary's right to choose when they would prefer to have medically necessary care provided in-person rather than through electronic exchange (that is, through electronic information and telecommunications technology). Further, our telehealth credit proposal does not count telehealth-only providers as equal to providers that deliver in-person care. We limited the impact that supplementing a network with telehealth providers could have on the network adequacy standards by offering a 10-percentage point credit, while

maintaining the maximum time and distance standards required for the applicable provider types. We believe this approach appropriately incentivizes MA organizations to contract with providers that offer additional telehealth benefits and maintains standards that ensure that in-person providers are within a reasonable time and distance for most beneficiaries.

Comment: Some commenters suggested that CMS modify the telehealth credit by increasing the credit to as high as a 20-percentage point credit.

Response: Our proposal attempted to strike the proper balance between incentivizing MA organizations to contract with providers that offer additional telehealth benefits while also maintaining adequate access to in-person care for the same provider specialties. Therefore, we proposed a 10-percentage point credit towards the percentage of beneficiaries residing within maximum time and distance standards. We believe a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage threshold because telehealth providers add value to a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80 to 89 percent range. We believe an increase to a 20-percentage point credit would be too significant at this time. We plan to observe the frequency and impact of this telehealth credit in network adequacy reviews and will consider adjusting this percentage in the future as needed.

Comment: A few commenters recommended that CMS add to the applicable provider list of dermatology, psychiatry, cardiology, neurology, and otolaryngology proposed at § 422.116(d)(5) by also including the provider types of ophthalmology, allergy and immunology, nephrology, primary care, gynecology, endocrinology, infectious diseases, or making all provider types applicable for the telehealth credit. Commenters encouraged CMS to expand the

list of specialty providers to account for advances in medical technology and promote beneficiary choice in how to receive medical services.

Response: We appreciate commenters' suggestions on expanding the list of applicable provider types for this telehealth credit. As we explained in the previous comment response, we believe the telehealth credit amount is properly balanced to maintain adequate access to in-person care while also incentivizing MA organizations to contract with telehealth providers. We note that in the proposed rule, we did not believe it was necessary to take telehealth into account for primary care providers. 85 FR 9099. However, the use of and access to primary care doctors via telehealth, as well as other provider specialties highlighted by commenters (whose comments referred to circumstances outside the Public Health Emergency), has been critically important in delivering medical care to Medicare beneficiaries during the during the COVID-19 pandemic Public Health Emergency. Based on our experience during this emergency, we observed how important it is to have policies that encourage the widespread availability of telehealth services at all times. Additionally, President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) called for enhanced access to health outcomes made possible through telehealth services or other innovative technologies as a way to secure and improve Medicare. In light of the COVID-19 pandemic and this Executive Order, we now believe that we should expand the list of specialty provider types finalized at § 422.116(d)(5) and there is no reason to restrict this credit to only provider types that are the most apt to provide telehealth services or for which we have seen potential for failing to meet the specific time and distance standards. New medical technologies and treatments are rapidly evolving across various providers and we would like to broaden the scope of eligible providers to account for these developments by implementing recommendations from commenters on the

provider types in § 422.116(b)(1) that should be eligible for the telehealth credit. However, we also do not believe that it is appropriate to make this credit available to all provider types at this time. Therefore, based on the comments received, we are adding the following provider types to the list finalized at § 422.116(d)(5): Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/ OB/GYN, Endocrinology, and Infectious Diseases.

Comment: A few commenters recommended that we modify CMS's proposal at § 422.116(d)(5) to include 1876 cost plan telehealth providers that provide telehealth services through supplemental benefits.

Response: Our proposal at § 422.116(d)(5) limited the credit to providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks. As we pointed out in the proposed rule, additional telehealth benefits described at § 422.135 only apply to MA plans. For that reason, our proposal did not extend the 10-percentage point credit to cost plans. We believe this is appropriate because of the protections and rules that exist for additional telehealth benefits that require access to in-person care at the election of the enrollee. Telehealth services offered through supplemental benefits are not subject to these rules and may be too limited in scope to warrant a credit for network adequacy. Therefore, we are finalizing this telehealth credit as proposed at § 422.116(d)(5).

Comment: We received numerous comments in support of our proposal at § 422.116(d)(6) that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anticompetitive restrictions, that limit the number of providers or facilities in a county or state. Some commenters expressed agreement with our discussion in the proposed rule that CON laws have a

negative impact on network adequacy, reduce competition, result in higher prices and lower patient access. Other commenters opposed the “CON law credit” and disagreed with our viewpoint on the impact that CON laws. Opposing commenters suggested that CON laws are not a significant barrier to providers in underserved areas and help assure that there is not an overabundance of specialized facilities that need to treat patients in order to remain in business, which causes an overutilization of services. These commenters were concerned that a 10-percentage point credit may hinder enrollee access to providers. We received some comments seeking clarification on the term “other anticompetitive restrictions” and the conditions under which the CON law credit will be available.

Response: We appreciate commenters’ varying viewpoints on CON laws and their impact on network adequacy. We continue to believe that CON laws adversely affect competition and free market entry, and therefore, MA organizations must pay more for benefits when there is a limited supply of providers or facilities. We believe the 10-percentage point credit is an appropriate adjustment to make for MA organizations that contract with providers or facilities that are affected by CON laws in counties and states. As previously mentioned, prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80 to 89 percent range. Like the telehealth credit, this credit does not reduce the maximum time and distance criteria required for specific providers or facilities; it reduces the compliance threshold that MA organizations must meet in order to meet our network adequacy standards. Even when this credit applies, MA organizations must still contract providers and facilities where a majority of beneficiaries reside within maximum time and distance standards.

We proposed that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected

provider and facility types in states that have CON laws, or *other state imposed anticompetitive restrictions*, that limit the number of providers or facilities in a county or state. We are implementing this network adequacy policy in furtherance of President Trump’s Executive Order 13890 on Protecting and Improving Medicare for Our Nation’s Seniors (October 3, 2019), which called for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain Certificate of Need (CON) laws or *other anticompetitive restrictions*. We clarify here that the term “anticompetitive restrictions” at § 422.116(d)(6) is meant to encompass state laws that restrict the provider or facility supply of specialty types listed at § 422.116(b), even if the state does not formally call them CON laws. For example, Wisconsin does not have a CON law, but has a limit on the maximum number of approved hospital beds.⁵²

Additionally, we clarify that CMS will identify the states, counties and provider/facility specialty types where the CON law credit will be available for MA organizations. CMS has conducted comprehensive research on every state to determine whether the state uses CON laws or other anticompetitive restrictions and whether those laws affect the provider or facility types in our network adequacy standards at § 422.116(b). As we have described in regulation text, CMS may customize base time and distance standards in states with CON laws in lieu of allowing for the 10-percentage point credit. We clarify here and in regulation text at § 422.116(d)(6), that CMS may use customization when necessary due to utilization or supply patterns. Therefore, the 10-percentage point credit will not be allowable in counties where the specific provider or facility type maximum time and distance standards have already been customized. CMS will use the HPMS Network Management Module to identify the county and

⁵² <http://docs.legis.wisconsin.gov/statutes/statutes/150/VII/93>

provider/facility combinations that are eligible for this 10-percentage point credit and MA organizations will need to submit a credit request for each provider or facility type they believe has been affected by the CON or anticompetitive laws.

Therefore, we are finalizing at § 422.116(d)(6) that in a state with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the state or a county in the state, CMS will either award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

Comment: We received some comments about the cumulative effect of the telehealth and CON law credits on the percentage of beneficiaries residing within published time and distance standards. Some commenters questioned whether it was allowable to combine the two credits and others expressed concern with the effect of combining the two credits. Commenters were concerned that the combined change in the compliance percentage would likely have adverse impacts on provider access and choice.

Response: When discussing the CON law credit in the proposed rule, we stated that the CON law credit could be “in addition to” the telehealth credit, when applicable. We confirm that interpretation here and reiterate that both of these credits may be applied together to the percentage of beneficiaries residing within maximum time and distance standards at § 422.116(d)(4). We note that these credits do not reduce the actual maximum time and distance standards themselves, and that CMS still requires that MA organizations contract with providers where a majority of beneficiaries (that is, no less than 65 percent in rural counties, and 70 percent in non-rural counties, when both credits apply) reside within maximum time and distance

standards for in-person access to care when needed. Additionally, we reiterate that § 422.112(a) requires that MA organizations must ensure that all covered services are available and accessible under the plan and that MA organizations must maintain a network of providers to provide adequate access to covered services and must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable or the network is inadequate.

Comment: A few commenters recommended changes to our proposed exceptions process. Some commenters recommended that CMS shift from categorically treating an “inability to contract” as an invalid rationale for an exception and instead consider it a valid rationale relating to consolidated or concentrated provider markets. Others recommended that CMS consider exceptions based on documented provider activities that have resulted in anticompetitive practices impeding efforts to meet network adequacy standards. Another commenter suggested that where there may be repeated exception requests based on geographical barriers, CMS should consider granting permanent exceptions. Finally, a commenter requested that CMS revise its language in § 422.116(f) to expressly provide for exceptions for I-SNPs because they commonly furnish services in long-term care facilities.

Response: Under our proposal, an MA organization may request an exception when two criteria are met. First, certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; second, the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria but are currently available and accessible to most enrollees, consistent with the local pattern of care. We explained in the proposed rule the meaning of “available” by providing examples, such as when

the provider has moved or retired, or when the provider/facility does not contract with any organizations or exclusively with another organization. (85 FR 9102 - 9103). However, we distinguish these examples from situations where an MA organization is unable to successfully negotiate and establish a contract with a provider or facility, which we refer to as the “inability to contract.” The non-interference provision at section 1854(a)(6) of the Act prohibits us from requiring any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, we cannot assume the role of arbitrating or judging the bona fides of contract negotiations between an MA organization and available providers or facilities. With respect to comments about “documented provider activities that have resulted in anticompetitive practices,” we believe that commenters are also referring to price negotiations between MA organizations and providers. We maintain that the “inability to contract” with an available provider or facility is not a valid justification for an exception at § 422.116(f). Therefore, we will generally not accept an organization’s assertion that it cannot meet our network adequacy criteria because providers/facilities are not willing to contract with it.

With respect to comments about permanent exceptions for geographic barriers, we clarify here that we would not create a “permanent” exception, as this would unnecessarily burden the exception process. Instead, we would utilize our customization process to recalibrate maximum time and distance requirements in accordance with the local pattern of care. As mentioned in our discussion about customization, we use information received through exception requests to stay informed and determine which counties or provider/facility types require a permanent adjustment in maximum time and distance standards through customization to account for things such as geographic characteristics or changes in supply.

Finally, we reiterate here that we do not believe it is necessary to change network adequacy standards based on the plan types that we review. Beneficiaries may still need to travel to another facility to receive specialized care or the specialty providers may need to travel to deliver the care to the long-term care facility. As a result, we do not believe any specific exceptions are needed for I-SNPs.

We proposed to codify the three criteria that we consider when evaluating exception requests at paragraphs (f)(2)(i), (ii) and (iii); that CMS considers whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; there are other factors present, in accordance with §422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and approval of the exception is in the best interests of beneficiaries. We reiterate that all three criteria must be met for CMS to approve an exception. We are finalizing the exceptions process and these criteria at § 422.116(f) as proposed.

Comment: Some commenters, in connection with a proposal to revise § 422.502 to address how CMS would use an entity's past performance on an MA contract in evaluating applications for new plans or service area expansions, stated that CMS should be more specific about what is and is not a basis for denying applications in connection with network adequacy in order to minimize uncertainty and unpredictability for MA organizations. Commenters suggested that CMS should add other and more specific criteria for use in considering applications.

Response: Although we are not addressing in this final rule the proposal to revise § 422.502 to address our use of information about past performance in evaluating an application, we understand that our statement in the proposed rule about how we would require an entity

applying for a new MA contract to provide an attestation about the adequacy of its network could be seen as touching on that topic. We will address our proposal about § 422.502 in a future final rule, but believe that additional clarity regarding attestations about meeting the network adequacy regulation and how they would be used in the context of applications for new MA contracts or service area expansions should be addressed as part of our network evaluation regulation.

We proposed specific regulation text (which we are finalizing) in § 422.116(a) that each network-based MA plan must demonstrate that it has an adequate contracted provider network. In addition, we proposed that when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year (85 FR 9093). We explained that we anticipated requiring such attestation in the MA organization's application or contract for a given year but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

Under our current network adequacy policy, as described in the PRA approved collection of information titled, "Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans" (CMS-10636) and referenced in our proposed rule, we removed network reviews from the application process beginning in 2018 for contract year 2019. Therefore, failures detected during network reviews are no longer used as a basis to deny an MA application. In the proposed rule, we made clear that an attestation could be used in connection with applications. In light of the comments discussed above, and to address the intersection of our regulations regarding network adequacy and the bases for denying applications, we are finalizing regulatory text to explicitly provide that we do not require information other than an

attestation regarding compliance with network adequacy requirements as part of the application for a new or expanding service area and will not deny such an application on the basis of such requirements. This provides greater clarity regarding how network adequacy and the application process intersect by codifying the current practice of relying on other mechanisms, such as our triennial reviews, to evaluate compliance with the specific network adequacy standards finalized in § 422.116 and to enforce those standards. The provision we are finalizing here at § 422.116(a)(1)(ii), however, does not prohibit CMS from considering or using information about an entity's failure to comply with a MA contract for purposes of an application denial when or if that compliance failure was associated with access to services or network adequacy evaluations and resulted in the imposition of an intermediate sanction or civil money penalty under to part 422 subpart O, with the exception of a sanction imposed under § 422.752(d). Therefore, we are finalizing regulatory text at § 422.116(a)(1)(ii) that CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments summarized earlier, we are finalizing the proposed changes to §§ 417.416(e)(3) and 422.116 with the following modifications:

- We are finalizing regulatory text at § 422.116(a)(1)(ii) that CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area. Accordingly, we

are designating the text we proposed at paragraph (a)(1) as paragraph (a)(1)(i) in the final regulation.

- We are not finalizing § 422.116(a)(3)(ii), which clarified the definition of the facility type Outpatient Dialysis.

- We are not finalizing Outpatient Dialysis in the list of facility specialty types at § 422.116(b)(2) and are finalizing the list of other facility-types as proposed but with different numbering, accordingly.

- We are not finalizing the base maximum time and distance standards for Outpatient Dialysis for all county designations at § 422.116(d)(2).

- We are finalizing the customization process at § 422.116(d)(3) with a modification that describes what triggers customization by CMS.

- We are finalizing § 422.116(d)(5) as proposed with the addition of Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/ OB/GYN, Endocrinology, and Infectious Diseases provider specialty types to the list of provider types for which the telehealth credit is available.

- We are finalizing § 422.116(d)(6) with a modification that describes when CMS may use the customization process as it relates to Certificate of Need or other anticompetitive laws.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40)

1. Part C Special Election Periods (§ 422.62)

Section 1851(e)(4) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in a Medicare Advantage (MA) plan or discontinue the election of an MA plan and change his or her election to original

Medicare or to a different MA plan. We have codified SEPs for the following circumstances specifically addressed in section 1851(e)(4) of the Act:

- SEP for Non-renewals or Termination.
- SEP for Changes in Residence.
- SEP for Contract Violation.

Section 1851(e)(4)(D) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions. This authority is codified at § 422.62(b)(4). CMS has historically included in regulation those SEPs that the statute explicitly authorizes and has established the SEPs for exceptional circumstances in our subregulatory guidance rather than through regulation.

We proposed to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Consistent with § 422.68(c), we also proposed to revise § 422.68(d) to clarify that for SEPs that are described in § 422.62(b), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted.

The proposed MA SEPs are summarized below. (Readers should refer to the proposed rule for more detail on these SEPs.):

SEP for Employer/Union Group Health Plan (EGHP) Elections. We proposed to revise § 422.62(b)(4) to codify a SEP for individuals making MA enrollment requests into or out of employer sponsored MA plans, for individuals to disenroll from an MA plan to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan.

SEP for Individuals Who Disenroll in Connection with a CMS Sanction. At new § 422.62(b)(5), we proposed to codify the SEP for individuals enrolled in an MA plan offered by an MA organization that is sanctioned by CMS.

SEP for Individuals Enrolled in Cost Plans that are Non-renewing their Contracts. At new § 422.62(b)(6), we proposed to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives.

SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE). At new § 422.62(b)(7), we proposed to codify the SEP allowing an MA plan enrollee to disenroll from an MA plan at any time in order to enroll in PACE.

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period. We proposed, at new § 422.62(b)(8), to codify the SEP for individuals who are eligible for guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act upon disenrollment from the MA plan in which they are enrolled.

SEP for Individuals with ESRD Whose Medicare Entitlement Determination Was Made Retroactively. We proposed to codify at new § 422.62(b)(9) that individuals whose Medicare entitlement determination based on ESRD was made retroactively would have a SEP to prospectively elect an MA plan offered by the MA organization, provided they met certain requirements.

SEP for Individuals Whose Medicare Entitlement Determination Was Made Retroactively. We proposed, at new § 422.62(b)(10), to codify a SEP for individuals whose Medicare entitlement determination was made retroactively.

SEP for Individuals Who Lose Special Needs Status. At new § 422.62(b)(11), we proposed to codify the SEP for individuals enrolled in an MA special needs plan (SNP) who are no longer eligible for the SNP because they no longer meet the applicable special needs status.

SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility. At new § 422.62(b)(12), we proposed to codify a SEP for individuals who belong to a qualified State Pharmaceutical Assistance Program (SPAP) to make one election to enroll in an MA-PD plan each calendar year.

SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP. At new § 422.62(b)(13), we proposed to codify the SEP allowing individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C-SNP) designed to serve individuals with those conditions.

SEP for Disenrollment from Part D to Enroll in or Maintain Other Creditable Coverage. At new § 422.62(b)(14), we proposed to codify the SEP that provides an opportunity for individuals to disenroll from an MA-PD plan (only by electing Original Medicare or an MA-only plan) in order to enroll in or maintain other creditable drug coverage (such as TRICARE or VA coverage) as defined in § 423.56(b).

SEP to Enroll in an MA Plan with a Star Rating of 5 Stars. At new § 422.62(b)(15), we proposed to codify the SEP allowing an eligible individual to enroll in an MA plan with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating.

SEP for Non-U.S. Citizens who Become Lawfully Present. At new § 422.62(b)(16), we proposed to codify the SEP for non-U.S. citizens who become lawfully present in the United States.

SEP for Providing Individuals who Requested Materials in Accessible Formats Equal Time to Make Enrollment Decisions. We proposed to codify, at new § 422.62(b)(17), a SEP for situations where an MA organization or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format.

SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster. We proposed to codify, at new § 422.62(b)(18), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period.

SEP for Significant Change in Provider Network. At new § 422.62(b)(23), we proposed to codify the SEP that is available when CMS determines that mid-year changes to an MA plan's provider network are significant, based on the effect on, or potential to affect, current plan enrollees' continued access to covered benefits.

SEP for Individuals Enrolled in a Plan Placed in Receivership. We proposed to establish a new SEP, at new § 422.62(b)(24), for individuals enrolled in plans offered by MA organizations experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the organization in receivership.

SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. We proposed to establish a new SEP, at new § 422.62(b)(25), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 422.166(h)(1)(ii).

SEP for Individuals Affected by a Federal Employee Error. At new § 422.62(b)(21), we proposed to codify a SEP for individuals whose enrollment or non-enrollment in an MA-PD plan is erroneous due to an action, inaction or error by a federal employee.

SEP for Other Exceptional Circumstances. Lastly, we proposed to retain the authority currently at § 422.62(b)(4) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 422.62(b)(26).

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we proposed to codify the following SEPs currently outlined in subregulatory guidance that coordinate with Part D election periods:

SEP for Individuals Who Experience an Involuntary Loss of Creditable Prescription Drug Coverage. At new § 422.62(b)(19), we proposed to codify the SEP for individuals who experience an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable but not including any such loss or reduction due to a failure to pay premiums.

SEP for Individuals Who Are Not Adequately Informed of a Loss of Creditable Prescription Drug Coverage. At new § 422.62(b)(20), we proposed to codify a SEP for individuals who are not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage.

SEP for Individuals Eligible for an Additional Part D IEP. At new § 422.62(b)(22), we proposed to codify the SEP for an individual who is eligible for an additional Part D Initial Enrollment Period (IEP) to have an MA SEP to coordinate with the additional Part D IEP.

These proposed revisions would codify existing subregulatory guidance for SEPs that MA organizations have previously implemented and are currently following, except the SEP for

Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer. We also proposed minor editorial changes in § 422.62(b) and (c), such as changing “Original Medicare” to “original Medicare.”

In general, we received support for the proposed SEPs. We received specific comments on the following proposed SEPs. (Comments that apply to SEPs proposed for both MA and Part D will be addressed in this section and not repeated in the Part D SEP section.) The comments on those proposals and our responses follow:

SEP for Employer/Union Group Health Plan (EGHP) Elections

Comment: A commenter recommended that we revise the current description of this SEP, which is that it is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan, and change it to indicate that it is available to individuals who have (or are enrolling in) an employer or union sponsored plan.

Response: We interpret this comment as a request to ensure that this SEP is available to individuals who have (or are enrolling in) an employer or union sponsored plan that is not an MA plan. As proposed, this SEP is available to individuals who are moving from employer or union coverage of any kind to an employer or union sponsored MA plan. In addition, the SEP is available to individuals who wish to disenroll from an MA plan to take employer or union sponsored coverage of any kind. As such, we believe the comment is addressed by the SEP, as proposed.

Comment: A commenter recommended that CMS codify the retroactive effective date guidelines related to this SEP, which are referenced in subregulatory guidance. Specifically, where there is a delay between the time in which the member completes the enrollment or

disenrollment request with the EGHP and when it is ultimately received by the health plan, the current guidelines indicate that the effective date may be retroactive up to, but may not exceed, 90 days from the date the MA organization received the request from the employer or union group. The disenrollment effective date guidelines indicate up to 90 days' retroactive payment adjustment is possible in cases where the EGHP does not provide the plan with timely notification of a member's requested disenrollment.

Response: We did not propose to codify a provision for retroactive payment adjustment due to employer or union delays in providing the MA organization with timely notification of a member's requested disenrollment, and we decline to adopt such a provision at this time. It has been CMS' longstanding expectation that in the event an MA organization chooses to delegate to an employer or union the collection and initial processing of beneficiary enrollment and disenrollment requests, the MA organization's agreement with the employer or union would require the employer or union to meet enrollment and disenrollment processing timeliness requirements that ensure the timely submission of enrollment and disenrollment requests. As such, retroactivity is necessary when the employer or union fails to meet these processing timeliness requirements.

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period

Comment: A commenter who expressed support for this proposal urged CMS to ensure that beneficiaries under age 65 with ESRD who have guaranteed issue rights under state laws and rules are aware of them.

Response: We appreciate the commenters' support and agree that education and outreach are essential for individuals to understand their enrollment options. We will continue to partner

with existing stakeholders to ensure that clear and comprehensive information is provided to beneficiaries so they are able to make an informed coverage choice.

SEP for Individuals Affected by a Federal Employee Error

Comment: A commenter, citing some stakeholder concerns regarding the 2019 redesign of the Medicare Plan Finder (MPF) tool, requested that CMS articulate in regulatory language (either in the SEP for individuals affected by a federal employee error or a separate entry) that a SEP for exceptional circumstances may exist when there are errors in the MPF or other CMS-issued or managed information platforms that beneficiaries used when making their decisions.

Response: We appreciate the comment. As the MPF and other CMS-issued or managed information platforms are the responsibility of the federal government, a beneficiary who relied on erroneous information on these platforms would be eligible for this SEP. As a result, we do not see a need to revise the current regulatory text or establish a new, separate SEP.

SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster

Comment: A number of commenters supported the proposal to codify this SEP and many of them recommended that it be expanded to address State-declared emergencies and public health emergencies such as COVID-19. A commenter questioned if the SEP would apply when FEMA provides fire management assistance. Commenters also requested that the end date should be revised so that the SEP is available to eligible individuals in cases where the emergency is declared with a retroactive effective date and/or lasts for more than 4 months.

Response: We appreciate the comments and agree that eligibility for this SEP should not be solely contingent upon a FEMA declaration. Based on these comments and consistent with our goal of providing an enrollment or disenrollment opportunity to an individual who missed an

election period due to circumstances beyond his or her control, we will revise the proposed SEP to include any emergency declaration issued by a Federal, state, or local government entity in response to a disaster or other emergency. This would not include instances in which fire management assistance is provided by FEMA, as this occurs prior to the declaration of an emergency or major disaster as part of state and/or local government efforts to stop the spread of fire and mitigate fire risk to the built environment, and is not itself an emergency declaration. We also agree with the comment that the SEP end date should be revised so that the SEP is available to eligible individuals in cases where the emergency is declared with a retroactive effective date and/or lasts for more than four months. We believe that the SEP end date should be related to the end of the emergency period, not the start of the emergency period.

As such, in §§ 422.68(b)(18) and 423.38(c)(23) we will change the scope of the SEP so that it applies to FEMA-declared emergencies/disasters, as well as disaster or other emergency declarations issued by a federal, state or local government entity. It will be available in the geographic areas identified in the emergency/disaster declaration. We also specify in this paragraph that the SEP will—

- Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
- End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. This 2-month period is consistent with other longstanding SEPs such as the SEP for Significant Change in Provider Network and the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively.

In finalizing the SEP with these revisions, we will retain the requirement that the individual was eligible for an election period at the time of the incident period and did not make an election during that election period because he or she was prevented from doing so due to the incident. We will refer to this SEP as the *SEP for Government Entity-Declared Disaster or Other Emergency*.

SEP for Individuals Enrolled in a Plan Placed in Receivership.

Comment: A commenter stated that it is unclear how an MA organization might know if another MA organization is having financial problems during the enrollment period and, therefore, would not know if a beneficiary is eligible for this SEP.

Response: The SEP is available only to individuals enrolled in a plan offered by an organization that has actually been placed into receivership, which, in our experience, is always a well-publicized event in the impacted area, usually involving a high level of media attention. We believe that MA organizations offering plans in the area in which another MA organization has been placed into receivership will be aware of such an event through its normal course of business in the areas it serves. When a beneficiary requests enrollment on the basis of their current plan being placed into receivership, the new plan can accept the beneficiary's verbal or written attestation as proof of their eligibility for this SEP.

Comment: Two commenters suggested that CMS allow MA plans and Part D sponsors to accept verbal beneficiary attestation as proof of eligibility for this SEP and not require additional proof of election eligibility. They believed that allowing verbal beneficiary attestation will expedite enrollment processing and may reduce enrollment denials. Additionally, they believed it would be consistent with current SEPs permitting verbal attestation for election period eligibility, such as the SEPs for Change in Residence, EGHP, etc.

Response: We did not propose that additional proof of eligibility for this SEP be required. Consistent with longstanding policy regarding eligibility for any SEP, an applicant's written or verbal attestation of SEP eligibility is sufficient.

SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer

Comment: A commenter, who expressed support for this new SEP and the new SEP for Individuals Enrolled in a Plan Placed in Receivership, requested that if a beneficiary who is eligible for these new SEPs or any other SEP has an agent of record, that a pathway be created for the agent of record to make the plan change.

Response: Beneficiaries are not precluded from using an agent/broker or any other available means to enroll in a plan when the beneficiary qualifies for a SEP.

Comment: Another commenter who expressed support for this new SEP and the new SEP for Individuals Enrolled in a Plan Placed in Receivership stated that impacted beneficiaries should be able to make elections utilizing these new SEPs only through contacting CMS directly, adding that to include these two new SEPs on plan enrollment forms, enrollment websites and other enrollment mechanisms is an unnecessary burden. The commenter believed that adding two new SEPs would be confusing for beneficiaries, as there are already numerous SEPs for beneficiaries to understand. This commenter also stated that the two new SEPs should be available to beneficiaries only outside of the Annual Enrollment Period (AEP) and only until such time as CMS terminates its contract with the plan. The commenter stated that an MA parent organization would not be able to identify a plan that has been identified by CMS as a consistent poor performer or a plan that has been placed in receivership and requested that CMS not require plans to offer these two new SEPs until contract year 2022.

Response: We appreciate the comment and believe that any potential beneficiary confusion can be minimized by presenting these two new election opportunities to beneficiaries in a clear and accurate manner. We believe that it is important that the SEPs be available throughout the year, not just outside of the AEP, given the effective date implications. That is, if a beneficiary finds it necessary to change plans during October or November using one of these SEPs, their new coverage should be effective the next month and they should not have to wait until January 1 or later. We disagree with the commenter and do not believe that it is an unnecessary burden to mention these two SEPs in plan materials where other SEPs are listed, such as the Attestation of Eligibility for an Enrollment Period. Exclusion of the two new SEPs would result in beneficiaries not being fully aware of all potential election periods available to them. With regard to the comment that an MA parent organization would not be able to identify a plan that has been identified by CMS as a consistent poor performer, we note that since plans are able to accept a verbal or written attestation from the beneficiary that they are eligible for a SEP, plans are able to accept a verbal or written attestation regarding eligibility for the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. In addition, plans are able to verify another organization's LPI status via the Medicare Plan Finder or the released Star Rating summary report. As a result, we do not see a reason to delay the offering of these two new SEPs until contract year 2022.

SEP for Significant Change in Provider Network

Comment: A commenter suggested that CMS revise this SEP so that it may be used when an individual plan enrollee's provider is terminated without cause, adding that while there is an existing SEP for significant change in an MA provider network, it is only triggered when a

threshold of terminations is met. The commenter states that an individual may have joined a plan specifically because their provider contracts with it, or have developed a relationship with that provider they wish to maintain.

Response: We appreciate the comment. As stated in the proposed rule, CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations. CMS appreciates that an individual would want to maintain a relationship with an individual provider, however, an individual provider's termination from a plan would not disrupt or affect that enrollee's continued access to covered benefits. CMS continues to believe this SEP is best reserved for network changes that are significant and have the potential to affect the access of covered benefits for a large number of enrollees.

SEP for Individuals with ESRD Whose Medicare Entitlement Determination Was Made Retroactively

Comment: Two commenters supported the proposal to codify a SEP for individuals with ESRD whose Medicare entitlement determination was made retroactively because it would allow beneficiaries to enroll who were not able during the customary period, as well as ensure that beneficiaries may enroll into an MA plan if certain conditions are met prior to the MA ESRD enrollment rule taking effect in 2021. Both commenters recommended that educational outreach be made to individuals with ESRD.

Response: We appreciate the commenters' support and agree that education and outreach are essential for individuals to understand their enrollment options. We will continue to partner with existing stakeholders to ensure that clear and comprehensive information is provided to beneficiaries so they are able to make an informed coverage choice.

SEP for Other Exceptional Circumstances

Comment: A commenter expressed strong support for CMS' statement that it retains the ability to grant case-by-case exceptional circumstance SEPs, and that the list at § 422.62(b)(26) is not exhaustive. The commenter expressed concern that leaving the creation of new SEPs solely to rulemaking will mean that it will take longer to implement new, necessary SEPs should the need arise and will make the agency's response less nimble and may hinder its ability to quickly meet the needs of beneficiaries. The commenter urges CMS to reiterate, or otherwise educate, plan sponsors, 1-800-MEDICARE counselors and CMS staff that despite exceptional circumstance SEPs now being codified, that such discretion still exists.

Response: We appreciate the commenters' support and continue to believe that it is important to retain the discretion to establish SEPs on a case-by-case basis. As such, at newly redesignated § 422.62(b)(26) and newly redesignated § 423.38(c)(34), we are finalizing our proposal to codify a SEP for other exceptional circumstances, which are, as stated in the proposed rule, situations in which it is in the best interest of the beneficiary that she or he be provided an enrollment (or disenrollment) opportunity. To date, CMS has used the existing authority at §§ 422.62(b)(4) and 423.38(c)(8)(ii) to assist individuals whose unique situations are outside the parameters of the existing SEPs, in order to address an individual's exceptional circumstances related to new enrollments or enrollment/disenrollment from an MA or Part D plan. These SEPs, which we also refer to as enrollment exceptions, are utilized when the reason is not captured in an existing SEP or specific circumstances require an exception to the predefined criteria. Consistent with current practice, CMS will consider granting an enrollment exception when one or more of the following factors is present:

++ Extraordinary Circumstances - Circumstances beyond the beneficiary's control that prevented him or her from submitting a timely request to enroll or disenroll from a plan during a valid enrollment period. This is inclusive of, but not limited to, a serious medical emergency of the beneficiary or their authorized representative during an entire election period, a change in hospice status, or mailed enrollment forms returned as undeliverable on or after the last day of an enrollment period.

++ Erroneous Election – Situations in which a beneficiary provides a verbal or written allegation that his or her enrollment in a MA or Part D plan was based upon misleading or incorrect information provided by a plan representative or State Health Insurance Assistance Program (SHIP) counselor, including situations where a beneficiary states he or she was enrolled into a plan without his or her knowledge or consent, and requests cancellation of the enrollment or disenrollment from the plan.

++ Plan Accessibility - A SEP may be warranted to ensure beneficiary access to services and where without the approval of an enrollment exception, there could be adverse health consequences for the beneficiary. This is inclusive of, but not limited to, maintaining continuity of care for a chronic condition and preventing an interruption in treatment.

CMS will review supporting details and documentation to determine eligibility for the SEP for exceptional circumstances, which, as currently implemented, can be in response to an individual beneficiary's request for an exception to the current enrollment rules, as well as CMS' determination that an exception is warranted for a group of beneficiaries. The SEP would take effect once CMS makes its determination and the enrollee has been notified. The effective date for an enrollment or disenrollment election using an approved enrollment exception would be based on the beneficiary's circumstances and may either be prospective or retroactive.

In addition to proposing to codify SEPs established in sub-regulatory guidance, as well as proposing two new SEPs (related to plans placed into receivership or being identified as a consistent poor performer), we requested comments on other SEPs that should be considered for codification. In response to that request, we received the following feedback:

Comment: A commenter urged us to establish a SEP for individuals in MA or Part D plans who are impacted by significant changes in their plan benefits from one year to the next, for example, significantly higher premiums or reduced benefits. They believed that this was particularly important for individuals with standalone PDPs since they do not have the same option to change plans during the first three months of the year afforded to those who begin the year enrolled in an MA plan (pursuant to the MA OEP). The commenter stated that most people who are enrolled in a given plan tend to rely on that plan remaining more or less the same, and, as a consequence, many people do not carefully scrutinize their Annual Notice of Change (ANOC) or other plan documents describing annual changes.

Response: Every Fall, CMS conducts a robust educational campaign that urges beneficiaries to review their plan benefits and make changes if their plan no longer meets their needs or if there are other options that could lower their out-of-pocket expenses. The ANOC is an important resource that plans are required to send to members detailing how benefits will change in the next plan year. Ultimately, it is the beneficiary's responsibility to assess their own drug and healthcare needs and determine if there is a better plan for them. We appreciate the commenter's concern, but will not be finalizing the suggested SEP.

Comment: Two commenters recommended that we establish a SEP for beneficiaries who have been accepted for admission to, or have been admitted to, an extended neoplastic disease care hospital and a physician has noted that the individual has life expectancy of ninety days or

less. The commenters stated that this was important because individuals who are diagnosed with advanced cancer are often at the end of their lives and should be able to disenroll from their MA plan to Original Medicare if the hospital where they choose to receive their care is outside of the plan's network. The commenters also noted that, as an alternative or an addition, CMS should determine extended neoplastic disease care hospitals to be "institutions" so that beneficiaries would be eligible for the Open Enrollment Period for Institutionalized Individuals (OEPI). The commenters noted that if this change was made, an additional revision should be made to waive the 90-day length of stay requirement.

Response: While we understand and are sympathetic to beneficiaries diagnosed with advanced cancer, we do not believe that the establishment of a new SEP is an appropriate remedy to this very specific situation. When establishing (and now codifying) SEPs, we look for broad scenarios where we believe it is imperative that beneficiaries have opportunities to join, change, or disenroll from plans. Beneficiaries who are not able to disenroll from their MA plan to return to Original Medicare still have access to Medicare Part A and Part B benefits. MA plans are required to cover all services covered by Original Medicare and if a member needs covered medical care that the providers in the plan's network cannot provide, the plan must cover care from an out-of-network provider.

The absence of neoplastic disease care hospitals from the list of facilities considered to be institutions is outside the scope of this proposal.

Comment: A commenter requested that we codify two SEPs that are in Chapter 2 of the Medicare Managed Care manual that were not included in the proposed SEPs in 42 CFR part 422: the SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals and the SEP for CMS and State-Initiated Enrollments. Similarly, they also requested that we codify two SEPs in

Chapter 3 of the Medicare Prescription Drug Benefit Manual that were not included in the proposed SEPs in 42 CFR part 423: the SEP for Full-Benefit Dual Individuals with Retroactive Uncovered Months and the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B.

Response: We appreciate the comments. The commenter requests that we codify in the Part C regulations the SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals that is included in Chapter 2 of the Medicare Managed Care Manual. We disagree that this SEP should be codified as a Part C SEP, as it is included in the Part C enrollment guidance merely as a reiteration of an already existing Part D SEP at § 423.38(c)(4). To codify this in the Part C regulations would result in the establishment of additional election periods that we did not intend to establish. The basis for the existing SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals is the fact that the beneficiary is (or has been) receiving the Part D low income subsidy, which is specific to Part D and why the SEP is codified in 42 CFR part 423 and not proposed as a SEP in part 422. Therefore, we decline to codify a SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals in the Part C regulations.

The commenter also requests that we codify in the Part C regulations the SEP for CMS and State-Initiated Enrollments that is included in Chapter 2 of the Medicare Managed Care Manual. This SEP is based on § 422.60(g)(5), which states that individuals who are passively enrolled by CMS into an MA-PD plan are eligible for the Part D SEP described in § 423.38(c)(10). To codify a new Part C SEP would be redundant; therefore, we decline the commenter's request to do so.

The commenter also requests that we codify in the Part D regulations the SEP for Full-Benefit Dual Eligible Individuals with Retroactive Uncovered Months that is included in Chapter

3 of the Medicare Prescription Drug Benefit Manual. As described in guidance, this SEP addresses the scenario in which a Part D eligible individual needs prescription drug coverage through the Limited Income Newly Eligible Transition (LI NET) program prior to his or her enrollment in a Part D plan, either by submitting an application to a plan or by being auto-enrolled by CMS into a plan for a future date. Since the process for establishing retroactive drug coverage through LI NET is a CMS-directed process, and does not involve an individual taking action to request enrollment in a plan, we did not propose to codify this SEP, and we decline to do so in this final rule.

Lastly, the commenter requests that we codify in the Part D regulations the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B that is included in Chapter 3 of the Medicare Prescription Drug Benefit Manual. As described in subregulatory guidance, individuals who are involuntarily disenrolled from an MA-PD plan due to loss of Part B but who continue to be entitled to Part A have a SEP to enroll in a PDP. The SEP begins when the individual is advised of the loss of Part B and continues for two additional months. We agree with the commenter that this SEP should be codified; the fact that it was not included in the proposed rule was an oversight. In response to this comment, we will codify at § 423.38(c)(33) the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B.

In addition to comments received on specific SEPs and suggested SEPs, we also received the general comments discussed below.

Comment: A commenter recommended that CMS codify its guidance from Chapter 2 of the Medicare Managed Care Manual (MMCM), section 30.4, that an organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility. The commenter stated that codifying this guidance

would be particularly helpful in instances where the SEP is based on factual circumstances such as the beneficiary's former plan is placed in receivership or has been consistently poor performing, and the beneficiary attestation is the easiest source of the information.

Response: In codifying these SEPs, we focused on what the SEPs were and detailed the situations when they would be applicable. We did not include in the proposed rule the codification of subregulatory guidance regarding attestation of SEP eligibility. We believe that details concerning the operational processing of enrollment requests are better suited for sub-regulatory guidance where we are able to go into more detail and provide examples and context. As such, we are declining the commenter's recommendation to codify guidance related to beneficiary attestations.

Comment: A commenter urged CMS to also consider that some beneficiaries may experience financial or enrollment difficulties stemming from the COVID-19 disruption. Concerned that some beneficiaries who have temporarily lost their Part B coverage for non-payment of premium may miss their opportunity to enroll through the open enrollment that ended in March 2020 due to staffing disruptions at local social security offices.

Response: We are aware that given the ongoing COVID-19 pandemic, stakeholders are looking for flexibilities for all aspects of Medicare enrollment and entitlement. However, it appears that the commenter is providing feedback regarding Medicare Part B enrollment and associated rules in 42 CFR part 407. We did not include in the proposed rule any new or revised regulations regarding Part B enrollment periods or loss of Part B coverage for non-payment of premium. We thank the commenter for their insights, but decline to address or modify any Part B enrollment rules given that they are outside the scope of this rulemaking.

Comment: A commenter stated that CMS should clarify whether the effective date for certain SEPs should be the first of the month following when the request is made. The commenter referenced SEPs such as the SEP for Individuals Who Disenroll in Connection with a CMS Sanction, the SEP for Individuals in PACE or the SEP for Individuals Who Dropped a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who are Still in a “Trial Period.” In addition, another commenter requested that we clarify the effective date for enrollment requests the organization receives from individuals eligible for the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively. As stated in the proposed rule, the effective date is the first day of the month following the MA organization’s receipt of the election, but cannot be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual. The commenter recommends that CMS permit retroactive enrollment based on when the beneficiary receives the notice of entitlement.

Response: We proposed to specify at §§422.68(d) and 423.40(c) that the effective date for elections made using SEPs described in §§422.62(b) and 423.38(c) is the first day of the calendar month following the month in which the election is made, unless otherwise noted. This applies to the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively as well, since it is not until an individual is notified of the Medicare entitlement determination that he or she, or an MA or Part D plan sponsor for that matter, would be aware of the determination and the Part A and/or Part B effective dates. We therefore disagree with the commenter that CMS should permit an enrollment to be retroactive to a date prior to when an individual received notification of Medicare entitlement or prior to the date the individual requests enrollment in the plan.

After considering the public comments, we are finalizing all MA SEPs as proposed, with the exception of the *SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster* at § 422.68(b)(18), which will be renamed the *SEP for Government Entity-Declared Disaster or Other Emergency*. This paragraph is being revised to change the scope of the SEP so that it applies to FEMA-declared emergencies, as well as emergency declarations issued by a federal, state or local government entity. We are also specifying in this paragraph that the SEP will—

- Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
- End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later.

In addition, we are adopting without modification the minor editorial changes in § 422.62(b) and (c) and the changes proposed at § 422.68 regarding effective dates of the SEPs.

2. Part D Special Election Periods (§ 423.38)

Section 1860D-1(b)(3) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may enroll in a stand-alone Part D prescription drug plan (PDP) or disenroll from a PDP and enroll in another PDP or in an MA plan that includes Part D benefits (MA-PD plan). We have codified SEPs for the following circumstances, which are explicitly discussed in the Act:

- SEP for Involuntary Loss of Creditable Prescription Drug Coverage.
- SEP for Individuals Not Adequately Informed about Creditable Prescription Drug Coverage.
- SEP for Enrollment/Non-enrollment in Part D due to an Error by a Federal Employee.

- SEP for Dual- and Other LIS-Eligible Individuals.
- SEP for MA-PD enrollee using the MA SEP65.

Section 1860D-1(b)(1)(B) of the Act directs us to adopt enrollment rules “similar to (and coordinated with)” those under Part C. Accordingly, in addition to those SEPs as previously described, we have applied certain SEPs established under the MA program to the Part D program. The SEPs from the MA program that have been codified for Part D include the following:

- SEP for Non-renewals or Terminations.
- SEP for Changes in Residence.
- SEPs for Contract Violation.

Section 1860D-1(b)(3)(C) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions, which is reflected at § 423.38(c)(8)(ii). Pursuant to this authority, we have previously codified SEPs for the following circumstances:

- SEP for Individuals Who Gain, Lose, or Have a Change in their Dual or LIS-Eligible Status.
- SEP for CMS and State-Initiated Enrollments.

CMS proposed to codify the following SEPs for exceptional circumstances, which are currently outlined in subregulatory guidance. Except as was noted in the proposed rule, our intent was to codify the current policy, and we solicited specific comment as to whether we overlooked any feature of the current policy that should be codified and if there were other exceptional circumstances we did not identify for which we should consider establishing a special election period.

We also proposed to revise § 423.40(c) to clarify that for SEPs that are described in § 423.38(c), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we noted that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

The proposed Part D SEPs are summarized below. (Readers should refer to the proposed rule for more detail on these SEPs.)

SEP for Employer/Union Group Health Plan (EGHP) elections. At new § 423.38(c)(11), we proposed to codify that individuals making enrollment requests into or out of employer sponsored Part D plans (PDPs), for individuals to disenroll from a PDP to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) would be eligible for a SEP to elect a PDP.

SEP for Individuals Who Disenroll in Connection with a CMS Sanction. At new § 423.38(c)(12), we proposed to codify the SEP for individuals enrolled in a PDP offered by a Part D plan sponsor that is sanctioned by CMS.

SEP for Individuals Enrolled in Cost Plans that are Non-renewing their Contracts. At new § 423.38(c)(13), we proposed to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives.

SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE). At new § 423.38(c)(14), we proposed to codify the SEP allowing individuals to disenroll from a PDP at any time in order to enroll in PACE.

SEP for Institutionalized Individuals. At new § 423.38(c)(15), we proposed to codify the SEP allowing individuals who move into, reside in, or move out of an institution, as defined at § 422.2, to enroll in or disenroll from a PDP.

SEP for Individuals Who Enroll in Part B during the Part B General Enrollment Period (GEP). At new § 423.38(c)(16), we proposed to codify the SEP for individuals who are not entitled to premium free Part A and who enroll in Part B during the GEP for Part B (January – March) for an effective date of July 1st to enroll in a PDP.

SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility. At new § 423.38(c)(17), we proposed to codify a SEP for individuals who belong to a qualified SPAP to make one election to enroll in a Part D plan each calendar year.

SEP for Disenrollment from Part D to Enroll in or Maintain Other Creditable Coverage. At new § 423.38(c)(18), we proposed to codify the SEP that provides an opportunity for individuals to disenroll from a Part D plan in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b).

SEP for Individuals Disenrolling from a Cost Plan who also had the Cost Plan Optional Supplemental Part D Benefit. At new § 423.38(c)(19), we proposed to codify that individuals who disenroll from a cost plan and the cost plan's optional supplemental Part D benefit would have a SEP to enroll in a PDP.

SEP to Enroll in a PDP with a Star Rating of 5 Stars. At new § 423.38(c)(20), we proposed to codify the SEP allowing an eligible individual to enroll in a PDP with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating.

SEP for Non-U.S. Citizens who become Lawfully Present. At § 423.38(c)(21), we proposed to codify the SEP for non-U.S. citizens who become lawfully present in the United States.

SEP for Providing Individuals who Requested Materials in Accessible Formats Equal Time to Make Enrollment Decisions. At § 423.38(c)(22), we proposed to codify the SEP in situations where the Part D plan sponsor or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format.

SEP for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster. At § 423.38(c)(23), we proposed to codify the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period.

SEP for Individuals Enrolled in a Plan Placed in Receivership. We proposed to establish a new SEP, at new § 423.38(c)(31), for individuals enrolled in a Part D plan offered by a plan sponsor that is experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the sponsor in receivership.

SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. We proposed to establish a new SEP, at new § 423.38(c)(32), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 423.186(h)(1)(ii).

SEP for Other Exceptional Circumstances. We proposed to retain the authority currently at § 423.38(c)(8)(ii) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 423.38(c)(34).

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we proposed to codify the following SEPs currently outlined in manual instructions that coordinate with Part C election periods:

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan, and Who Are Still in a Trial Period. We proposed to codify at new § 423.38(c)(24) a coordinating Part D SEP for individuals who disenrolled from their MA plan during their trial period (and have guaranteed issue rights).

SEP for an Individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to Disenroll from a MA-PD plan. At new § 423.38(c)(25), we proposed to codify that an individual disenrolling from an MA-PD plan has a SEP to request enrollment in a PDP.

Medicare Advantage Open Enrollment Period (MA OEP). At new § 423.38(c)(26), we proposed to codify that MA enrollees using the MA OEP would have a SEP to add or change Part D coverage.

SEP to request enrollment into a PDP after loss of special needs status or to disenroll from a PDP in order to enroll in an MA SNP. At new § 423.38(c)(27), we proposed to codify the SEP to request enrollment in a PDP for those who are no longer eligible for a SNP because they no longer meet the plan's special needs criteria.

SEP for Enrollment into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP. At proposed § 423.38(c)(28), we proposed to codify the SEP for both Part C

and Part D for those individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C-SNP) designed to serve individuals with those conditions.

SEP for Individuals Using the 5-Star SEP to Enroll in a 5-Star Plan without Part D Coverage. At new § 423.38(c)(29), we proposed to codify that individuals who use the 5-star SEP we proposed to be codified at § 422.62(b)(15) to enroll in a 5-star MA plan that does not include Part D benefits or a 5-star cost plan would have a SEP to enroll in a PDP or in the cost plan's optional supplemental Part D benefit.

SEP to enroll in a PDP for MA enrollees using the "SEP for Significant Change in Provider Network" to disenroll from an MA Plan. We proposed to codify at new § 423.38(c)(30) that MA enrollees using the "SEP for Significant Change in Provider Network" to disenroll from an MA plan (proposed at § 422.62(b)(23)) would be able to request enrollment in a PDP.

The revisions we proposed would codify existing subregulatory guidance for SEPs that Part D sponsors have previously implemented and are currently following, except for the *SEP for Individuals Enrolled in a Plan Placed in Receivership* and the *SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer*. We also proposed a few minor editorial changes in § 423.38(c), such as changing "3" to "three."

While most of the comments received on our SEP proposals related to SEPs that are applicable to both MA and Part D and, thus, were addressed above, we did receive one Part D-specific SEP comment.

Comment: While commenting on the proposed SEPs, a few commenters requested that we revisit the changes to the dual SEP finalized in April 2018 (83 FR 16514), when this SEP was changed from a monthly SEP to one that allows an individual to enroll in, or disenroll from, an

MA plan once per calendar quarter during the first nine months of the year. A commenter stated that an ongoing SEP for dual eligible individuals to enroll in either a FIDE SNP or a HIDE SNP would provide greater choice and access to integrated care options. Other commenters believed these beneficiaries needed the flexibility to change their healthcare coverage at any time during the year and viewed the previous ongoing dual SEP as an important beneficiary protection.

Response: As we noted in the April 2018 final rule, we understood that many commenters preferred an ongoing dual SEP, but we believed that adopting limitations was an appropriate step toward encouraging care coordination, achieving positive health outcomes, and discouraging extraneous beneficiary movement during the plan year. We were – and continue to be – mindful of the unique health care challenges that dual and other LIS-eligible beneficiaries may face. Under the revised rules, dual and other LIS-eligible beneficiaries continue to have additional flexibilities not afforded to other Part D-eligible beneficiaries and are able to make elections during the year. Given that our overall goals of improving administration of benefits and coordination of care have not changed, and we believe that continuity of enrollment helps us achieve these goals, we will not be revising the dual SEP at this time.

After considering the public comments, we are finalizing all SEPs as proposed, with the exception of the following:

- The SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster at §423.38(c)(23) will be renamed the SEP for Government Entity-Declared Disaster or Other Emergency. This paragraph is being revised to change the scope of the SEP so that it applies to FEMA-declared emergencies/disasters, as well as disaster or other emergency declarations issued by a federal, state or local government entity. We are also specifying in this paragraph that the SEP will—

- Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
- End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. This 2 month period is consistent with other longstanding SEPs.
- As discussed in the MA SEP section, at §423.38(c)(33) we are codifying the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B. This SEP is currently in subregulatory guidance, but was inadvertently omitted from the proposed rule.
- We are designating the SEP for Other Exceptional Circumstances from proposed § 423.38(c)(33) to § 423.38(c)(34).

In addition, we are adopting without modification the minor editorial changes in § 423.38(c) and the changes proposed at § 423.40 regarding effective dates of the SEPs.

VI. Technical Changes

A. Advance Notice and Announcement of Part D Risk Adjustment Factors (§ 423.329)

The Part D statute, and the regulations implementing the statute, specify that we must publish the Part D risk adjustment factors at the time of publication of the Part C risk adjustment factors (section 1860D-15(c)(1)(D) of the Act and § 423.329(b)(4)). We proposed to amend § 423.329(b)(4) to stipulate our intention to publish Part D risk adjustment factors using the process through which we would adopt, and announce the capitation rates and risk adjustment methodology for the MA program (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)).

The existing regulation codifying section 1860D-15(c)(1)(D) of the Act mirrors the statutory language of publishing Part D risk adjustment at the time of Part C risk adjustment

factor publication but does not specify the means by which CMS will do so. In the vein of the MMA, which added a new “Part D” to the Medicare statute (sections 1860D–1 through 42 of the Act), and directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program, CMS interpreted section 1860D-15(c)(1)(D) of the Act to mean that Part D risk adjustment factors should be published as part of the Advance Notice and Rate Announcement process used for Part C (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)). This amendment revises the regulation text to clarify our interpretation of the statute under which we will continue to publish Part D risk adjustment factors through the Advance Notice and Rate Announcement process. This final rule codifies the current interpretation of the statutory requirement and will not change how we propose and finalize the Part D risk adjustment model.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

B. Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes (§ 422.312)

In the February 18, 2020 proposed rule, we proposed a technical change to align the timeframes identified in § 422.312(b)(1) and (2) with the current statutory text (section 1853(b) of the Act). Section 1853(b) of the Act specifies the process through which we propose, adopt, and announce changes in risk adjustment methodology and capitation rates for the MA program. When first written, section 1853(b)(2) of the Act called for a 45-day advance notice period for the annual capitation rate and factors (for example, risk) used to adjust those rates and did not explicitly address a minimum comment period. However, the Securing Fairness in Regulatory

Timing Act of 2015 (Pub. L. 114-106) (SFRTA) amended section 1853(b) of the Act to require a 60-day advance notice period and a 30-day comment period.

The regulation implementing the advance notice and comment period, as written, mirrors the statute's original timeframe for issuance of the advance notice and requires only a 15-day comment period. While CMS adjusted operational practices to comply with current statutory requirements, we did not update the CFR provision. In this final rule, we update the advance notice of changes in methodology requirements at § 422.312(b)(1) and (2) by revising paragraph (b)(1) to refer to 60 days and paragraph (b)(2) to refer to 30 days, as stated in statute.

Comment: A commenter supported the proposal to revise the timeframes to follow the current statute to provide a 60-day advance notice period and a 30-day comment period. The commenter believes the 60-day timeframe allows more time for analysis and comment on methodology changes, including risk adjustment in MA.

Response: We thank the commenter for their support. We are finalizing this provision as proposed without modification.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information,” as defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our February 18, 2020, proposed rule (85 FR 9002), we solicited public comment on our proposed information collection requirements, burden estimates, and assumptions. We did not receive any such public comments as it pertains to the proposed information collection requirements, burden estimates, and assumptions that are being finalized in this rule.

However, five changes were made to this section based on our further consideration of these issues:

- We have added section VII.B.1. of this final rule specifically addressing information collection requirements regarding SSBCI.

- Section VII.A. of this final rule reflects wage updates for 2019 as well as the differences between the 2019 and 2018 rates. The changes in Table 2 were then used to update the estimates for each of the provisions.

- As discussed more fully in section VII.B.3. of this final rule regarding the impact of the ESRD provision, CMS expects a shortened enrollment form to be available starting in 2021. This enrollment form is expected to reduce the time burden for completing an enrollment form from 30 minutes to 20 minutes. This reduction affects the impacts of several provisions in this section.

- As discussed in the next few paragraphs, and as further detailed in the provisions whose impact is estimated in this section, the implementation of certain provisions finalized in this rule will be delayed compared to the proposal. This has resulted in recalculations that are specific to several provisions and discussed as appropriate in the respective sections.

- The implementation date for the contract limitation on existing D-SNP look-alikes finalized in § 422.514(d) has been delayed one year, as discussed in section II.B of this final rule. As a result, we assume that the burden related to this provision will take place over the two years prior to the implementation rather than one year, as we assumed in the proposed rule. The details are provided later in this section.

- This final rule does not finalize all provisions in the proposed rule. Given the need to focus our attention on more immediate regulatory actions, this final rule implements a subset of the provisions that were proposed in the February 2020 proposed rule. In this regard, we are limiting this rule to this set of provisions. The remaining proposals will be addressed in a separate final rule that we expect to publish later in 2020. Thus, the collection of information requirements are expected to be addressed as follows:

- Rule Number 1: PRA-related Requirements/Burden Finalized in this Rule

- ++ Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

- ++ Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

- ++ Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

- ++ Medical Loss Ratio (MLR) (§ 422.2440)

- ++ Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

- Rule Number 2: PRA-related Requirements to be Addressed Later in 2020

- ++ Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

- ++ Mandatory Drug Management Programs (DMPs) (§ 423.153)

- ++ Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

- ++ Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs

- ++ Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

- ++ Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

- ++ Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

- ++ Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

- ++ Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)

- ++ Appeals Requirements under PACE (§§ 460.122 and 460.124)
- ++ Documenting and Tracking the Provision of Services under PACE (§ 460.98)
- ++ Documentation in Medical Records under PACE (§ 460.210)
- ++ PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)
- ++ Stipulated Decisions in Part C (§ 422.562)

A. Wage Data

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics’ (BLS’s) May 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Actuaries	15-2011	58.16	58.16	116.32
All Occupations [used for impact on enrollees filling out forms]	00-0000	25.72	n/a	n/a
Business Operations Specialist, all others	13-1198	38.57	38.57	77.14
Compliance Officer	13-1041	35.03	35.03	70.06
Computer Programmers	15-1251	44.53	44.53	89.06
General Operations Manager	11-1021	59.15	59.15	118.30
Health Technician, All Other	29-9098	28.17	28.17	56.34
Office Support and Administrative Support	43-9199	18.41	18.41	36.82
Physician	29-1216	96.85	96.85	193.70

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs

vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries, we believe that the burden will be addressed under All Occupations (at \$25.72/hr) since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector wage adjustment, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2018 wages, this final rule uses BLS's May 2019 wages which are the most current as of the publication date of this rule. Changes to the adjusted wages represent shifts in average wages of occupations between 2018 and 2019 and are presented in Table 2. This table only contains wage estimates for occupations used in both the proposed rule and this final rule. However, provisions which were not estimated in the proposed rule but were estimated in the final rule require consideration of additional occupational titles beyond those in this table.

TABLE 2: COMPARISON OF PROPOSED AND FINALIZED ADJUSTED HOURLY WAGES

Occupation Title	Occupation Code	CMS-4190-P: May 2018 (\$/hr)	CMS-4190-F: May 2019 (\$/hr)	Difference (\$/hr)
Actuaries	15-2011	111.78	116.32	+4.54
All Occupations*	00-0000	24.98	25.72	+0.74
Business Operations Specialist, all others	13-1198	74.00	77.14	+3.14
Compliance Officer	13-1041	69.72	70.06	+0.34
Computer Programmers	15-1251	86.14	89.06	+2.92
General Operations Manager	11-1021	119.12	118.30	-0.82
Health Technician, All Other	29-9098	50.90	56.34	+5.44
Office Support and Administrative Support	43-9199	36.04	36.82	+0.78
Physician	29-1216	202.86	193.70	-9.16

*Represents the mean hourly rate for individuals which, as explained above, is not adjusted for fringe benefits and overhead.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VI) of this final rule.

1. ICRs Regarding Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

As explained in section II.A. of this final rule, CMS is finalizing provisions for furnishing SSBCI. In section II.A. of this final rule, CMS adopts a regulation to implement section 1852(a)(3)(D) of the Act, which authorizes MA plans to furnish special supplemental benefits exclusively to chronically ill enrollees, as defined in the statute. SSBCI are currently allowed in 2020.

In this final rule, we are finalizing four SSBCI provisions with paperwork burden. We are finalizing the proposed requirements at § 422.102(f)(3) requiring MA plans offering SSBCI to: (i) develop written policies for determining enrollee eligibility and document the determination that an enrollee is a chronically ill enrollee based on the definition in statute and regulation; (ii) make information and documentation related to determining enrollee eligibility available to CMS upon request; (iii) have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and document these criteria; and (iv) document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. We address the collection of information in a reorganized fashion to address the functions that are required by the regulation as a whole rather than by how the regulation is structured and codified. We address these required MA organization functions and activities as follows:

In this final rule, we are finalizing four SSBCI provisions with paperwork burden. We are finalizing the proposed requirements at § 422.102(f)(3)(i) through (iv) requiring MA plans offering SSBCI to:

(1) have written policies for determining enrollee eligibility to be considered chronically ill and must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI

(2) document in writing the criteria for determining enrollee eligibility for being considered chronically ill and must also document in writing the enrollee's eligibility to receive a particular SSBCI

(3) Make information and documentation related to determining enrollee eligibility available upon request

(4) document each determination that an enrollee is eligible to receive an SSBCI, and make information concerning enrollee eligibility criteria available to CMS.

In this section, we estimate the paperwork burden of each of these four functions required by the final regulation. The following changes will be submitted to OMB for approval under control number 0938-0763 (CMS-R-262).

a. Per § 422.102(f)(3)(i), plans must have written policies for determining enrollee eligibility to be considered chronically ill and, per paragraph (f)(3)(iii), must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

Since the authority to offer and cover SSCBI is already being implemented, we assume most MA organizations already have developed the required policies since it would be difficult to score the cost in their bids without having such policies. We similarly assume that most plans

have internal written memos documenting these criteria and that they have updated their systems to record enrollee eligibility for SSBCI (since without such documentation they would have no way of knowing when to reimburse providers for furnishing SSBCI to enrollees).

Therefore, this provision codifies existing practice.

However, even though we expect that the policies have already been developed, we have inadvertently neglected to account for the requirement and burden in any of our collection of information requests. We are correcting this oversight via this proposed and final rulemaking activity.

We estimate that it will take a team of one compliance officer (at \$70.06/hr), one physician (at \$193.70/hr), and one general operations manager (at \$118.30/hr) a total of 5 hours to develop the necessary policies. The team's hourly cost is \$382.06/hr ($\$70.06/\text{hr} + \$193.70/\text{hr} + \$118.30/\text{hr}$). In aggregate, the annual burden for 234 parent organizations is 1,170 hours ($234 \text{ plans} * 5 \text{ hrs}$) at a cost of \$447,010 ($1,170 \text{ hr} * \$382.06/\text{hr}$) or \$1,910 ($\$447,010/234$) per organization.

This is an annual requirement/burden since plan packages renew each year and the SSBCI criteria must therefore be reevaluated, including confirmation of existing criteria, each year.

b. Per §422.102(f)(3)(i), plans must also document in writing those criteria for determining enrollee eligibility for being considered chronically ill and, per §422.102(f)(3)(iii), must also document in writing the enrollee's eligibility to receive a particular SSBCI.

We estimate it will take 2 hours at \$56.34/hr for a health technician to document in writing the objective criteria for determining an enrollee's eligibility to be considered chronically

ill and to be eligible to receive a particular SSBCI. In aggregate, we estimate an annual burden of 468 hours (234 plans * 2 hr/plan) at a cost of \$26,367 (468 hrs * \$56.34/hr) or \$113 per plan.

This is an annual requirement/burden since documentation must be performed each contract year.

c. Per §422.102(f)(3)(iv), plans must also document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. To date, MA organizations have only been able to include non-primarily health related SSBCI in the plan offerings since January 1, 2020, during one contract year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Thus, our data is not indicative of future usage.

To offer SSBCI, a plan must determine, as defined in legislation, that an enrollee is chronically ill and that the items or services furnished under the SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. This determination would require a review of the enrollee's health records (for example, diagnosis codes, frequency of hospitalizations, and doctor's notes) as well as a determination and review by plan medical staff that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Thus the process may be partially automated with the remainder of the process requiring medical review. We accordingly must account for three contributions to total impact:

1) Initial creation of software, annualized over 3 years: Initially, software will be created to collect basic data elements (claims, diagnoses, hospitalizations, drug utilization) for physician review. We expect a team of three professionals: A compliance officer would identify categories

of eligible SSBCI, the physician would identify needed data elements for review, and the computer programmer would automate this part of the process. We expect a burden of 2,808 hours (234 parent organizations times 12 hours (8 hours for a programmer plus 2 hours for a compliance officer plus 2 hours for a physician)) at an annualized cost of \$96,717 ((1/3) times 2808 hours times a team wage of \$103.33/hr ([8 hours times \$89.06 (computer programmer)+(2 hours times 70.06 (compliance officer)+(2 hours times \$193.70 (physician))]/12).

2) Annual physician review of cases: We expect ongoing plan physician review in all years (including the first) to ascertain if the SSBCI is expected to have the desired impact on enrollees. We assume 3 hours of review per month per parent organization, resulting in 36 hours per parent organization per year. In aggregate, we expect a burden of 8,424 hours (234 parent organization times 36 hours per parent organization) at an annual burden of \$1,631,729 (8,424 hours times \$193.70/hr, physician wage).

3) Annual update of software: It would clearly be overly burdensome to review each SSBCI case. Thus as cases are reviewed, we expect the continual review of new cases to generate additional criteria that can be automated. We assume half the time for updates as for the initial first-year creation. We assume a burden of 1,170 hours (234 parent organizations times 5 hours (1 hour for a compliance officer plus 4 hours for a computer programmer) at a cost of \$99,754 (1170 hours times a team wage of \$85.26/hr ([4 hours times \$89.06(computer programmer) plus 1 hour times \$70.06 (compliance officer)]/5). Table 3 summarizes all burdens connected with SSBCI.

4) Make information concerning enrollee eligibility criteria available to CMS.

We are not requiring MA plans to report or submit this information on a regular or consistent basis to CMS. We do not intend to closely monitor or regularly request this

documentation and reiterate that MA plans will have discretion in designing which items and services to offer as SSBCI and for which chronically ill enrollees to cover them, so long as the statutory and regulatory standards are met. CMS intends to use this authority to collect information as necessary for program oversight, such as if there are specific, consistent, and/or severe complaints that an MA plan is violating the rules set forth in § 422.102(f). Based on our experience with serious plan complaints, we anticipate requesting no more than 5 plans per year to complete this task. Consequently, since this provision is expected to affect less than 10 entities per year, it is exempt from paperwork burden (5 CFR 1320.3(c)(4)). Table 3 summarizes the various burdens associated with SSBCI.

TABLE 3: SUMMARY OF BURDEN FOR SSBCI AT § 422.102

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Annual Cost (\$)
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Initial Software)	234	1	12	2808	103.33	96,717
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Physician review)	234	1	36	8424	193.7	1,631,729
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Software updates)	234	1	5	1170	85.26	99,754
SSBCI	422.102(f)(3)(ii)		Written criteria	234	1	2	468	56.34	26,367
SSBCI	422.102(f)(3)(iii)		Enrollee eligibility	234	1	9	2106	86.95	179,465
Total				234		Varies	14,976		2,034,032

2. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

The following changes will be submitted to OMB for approval under control numbers 0938-0753 (CMS-R-267) and 0938-NEW (CMS-10718). The requirements under CMS-R-267 are associated with burden on MA plans identified as D-SNP look-alikes under § 422.514(d) and (e) (see section VII.B.1.a. of this final rule). The requirements under CMS-10718 are associated with burden on the enrollees in these MA plans (see section VII.B.1.b. of this final rule).

We did not receive any comments on our proposed collection of information requirements and burden estimates; however, we are updating our proposed burden estimates to reflect the change in this final rule delaying the prohibition on the renewal of existing D-SNP look-alikes by one year. As indicated above in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

As described in section II.B. of this final rule, we are establishing new contract requirements that we believe are necessary to fully implement federal D-SNP requirements, especially those related to Medicare-Medicaid integration codified at §§ 422.2, 422.107, and 422.629 through 422.634 pursuant to the BBA of 2018. We are finalizing a prohibition on CMS entering into a new contract for plan year 2022 and future years for any non-SNP MA plan that projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX of the Act. Additionally, we are finalizing a prohibition for plan year 2023 and future years on CMS renewing an existing contract for any non-SNP MA plan that an MA organization offers that has actual enrollment, as determined by CMS in January of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX of

the Act, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

Our dually eligible enrollment threshold at § 422.514(d) will apply to any plan that is not a SNP as defined in § 422.2. We are applying this requirement only to non-SNP plans to allow for the disproportionate dually eligible enrollment that characterizes D-SNPs, institutional SNPs, and some chronic or disabling condition SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. The requirement is also limited to states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as a Medicare-Medicaid Plan (MMP). We are establishing this limitation because it is only in such states that the implementation of D-SNP requirements necessitates our new contracting requirements. That is, in a state with no D-SNP or comparable managed care plan, the D-SNP requirements have not had any relevance historically, and therefore the operation of a D-SNP look-alike does not have any material impact on the full implementation of federal D-SNP requirements.

The contract requirement based on the projected enrollment in the plan bid at § 422.514(d)(1) will prevent MA organizations from designing new D-SNP look-alikes. Under at § 422.514(d)(2), we will make the determination whether an MA organization has an existing non-SNP MA plan with actual enrollment exceeding the established threshold using the enrollment in January of the current year. Using data from the most recently available contract year, the 2020 bid submission process, we estimate that there are 67 MA plans that have enrollment of dually eligible individuals that is 80 percent or more of total enrollment. Of these

67 MA plans, 62 plans are in 19 states⁵³ where there are D-SNPs or comparable managed care plans and will be subject to § 422.514(d). These 62 plans projected a total enrollment of 180,758 for contract year 2020.

MA organizations will likely non-renew for plan year 2022 or 2023 those plans that exceed our criteria in § 422.514(d)(1) and (2). The MA organization has the opportunity to make an informed business decision to transition enrollees into another MA-PD plan (offered by it or by its parent organization) by: (1) identifying, or applying and contracting for, a qualified MA-PD plan, including a D-SNP, in the same service area; or (2) creating a new D-SNP through the annual bid submission process. We expect the vast majority of D-SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D-SNP look-alike, and we expect in rare instances that the non-renewing plan may choose to not transition enrollees.

The changes required of MA organizations based on this final rule impact D-SNP look-alikes (see section VII.B.1.a. of this final rule) and their enrollees (see section VII.B.1.b. of this final rule). While we cannot predict the actions of each affected MA organization with 100 percent certainty, we base our burden estimates on the current landscape of D-SNP look-alikes, the availability of D-SNPs or MA-PD plans under the same parent organization in the same service area, and the size and resources of the MA organization.

⁵³ These 62 plans are located in Arizona, Arkansas, California, Hawaii, Idaho, Illinois, Indiana, Louisiana, Michigan, Mississippi, New Jersey, New Mexico, North Carolina, Ohio, Oregon, South Carolina, Tennessee, Utah, and Washington.

a. MA Plan Requirements and Burden

As indicated, the following changes will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

At § 422.514(e), we are finalizing a process for an MA organization with a D-SNP look-alike to transition individuals who are enrolled in its D-SNP look-alike to another MA-PD plan offered by the MA organization, or by another MA organization with the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D-SNP look-alikes. Under this final rule, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in § 422.514(d)(2) could transition enrollees into another MA-PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization), as long as that receiving MA-PD plan meets certain criteria specified in § 422.514(e)(1)(i) - (iv). The process finalized at § 422.514(e) allows, but does not require, the MA organization to transition dually eligible enrollees from D-SNP look-alikes into D-SNPs and other qualifying MA-PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form. This transition process is conceptually similar with the proposed “crosswalk exception” procedures at § 422.530(a) and (b) as described in the proposed rule; however, this final rule allows the transition process to apply across contracts or legal entities and from non-SNP to SNPs provided that the receiving plan is otherwise be of the same plan type (for example, HMO or PPO) as the D-SNP look-alike.

While the contract limitation for existing D-SNP look-alikes begins in the 2023 plan year, we intend for the transition process to take effect in time for D-SNP look-alikes operating in

2020 and 2021 to utilize the transition process for enrollments effective January 1, 2021 or January 1, 2022, respectively. Based on the current landscape for D-SNP look-alikes, we believe the vast majority of D-SNP look-alikes are able to move current enrollees into another MA-PD plan using the transition process we are finalizing in this rule. We expect many of these plans will choose to transition membership for the 2022 and 2023 plan years. Therefore, we are assuming the burden of the 62 plans transitioning enrollees will happen for half the plans in 2021 (for a 2022 effective date) and half the plans in 2022 (for a 2023 effective date).

We estimate each plan will take a one-time amount of 2 hours at \$77.14/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D-SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D-SNP look-alikes that transition eligible beneficiaries into a D-SNP because they will not need to verify enrollees' Medicaid eligibility. The 2-hour time estimate accounts for any additional work to confirm an enrollee's Medicaid eligibility for D-SNP look-alikes transitioning eligible enrollees to a D-SNP. The burden for MA organizations to transition enrollees to other MA-PD plans during the 2021 and 2022 plan years is 124 hours (62 D-SNP look-alikes * 2 hr/plan) at a cost of \$9,565 (124 hr * \$77.14/hr). We averaged this burden for the 62 plans over the 2021 and 2022 plan years, resulting in an annual burden of 62 hours (124 hr/2 yr) at a cost of \$4,783 (\$9,565/2 yr).

The vast majority of MA organizations with existing D-SNP look-alikes also have an MA-PD plan with a premium of \$0 or a D-SNP in the same service area as the D-SNP look-alike. Consequently, we do not believe many MA organizations will choose to create a new D-SNP as a result of this final rule. The prevalence of existing MA-PD plans and D-SNPs also makes it unlikely that an MA organization will need to expand a service area for an existing MA-

PD plan or D-SNP. Therefore, we do not expect this provision to have further impact beyond the currently burden approved under control number 0938-0935 (CMS-10237) for creating a new MA-PD plan or D-SNP and expanding a service area.

As finalized in § 422.514(e)(2)(ii), the MA organization will be required to describe changes to MA-PD plan benefits and provide information about the MA-PD plan into which the individual is enrolled in the Annual Notice of Change (ANOC) that the MA organization must send, consistent with § 422.111(a), (d), and (e). Consistent with § 422.111(d)(2), enrollees will receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period (AEP). As each MA plan must send out the ANOC to all enrollees annually, we do not estimate that MA organizations will incur additional burden for transitioned enrollees. The current burden for the ANOC is approved under control number 0938-1051 (CMS-10260).

Additionally, we do not expect any plans will be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at § 422.514(e)(4), as we anticipate all MA organizations with D-SNP look-alikes will be able to transition their enrollees into another MA-PD plan (or plans). However, we are finalizing the requirement to ensure protection of enrollees if the situation does occur.

In subsequent years (2023 and beyond), we estimate that at most five plans per year will be identified as D-SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a state that will begin contracting with D-SNPs or other integrated plans. We believe that these plans would non-renew and transition their membership into another MA-PD plan or a D-SNP. Therefore, the annual burden for the 2023 plan year and subsequent years is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of \$771 (10

hr * \$77.14/hr) for a business operations specialist to transition enrollees into a new MA-PD plan.

The average annual burden for MA plans over three years is 45 hours ([62 hr+62 hr+10 hr]/3 yr) at a cost of \$3,446 ([\$4,783 + \$4,783 +\$771]/3 yr). The impact is summarized in Table 4.

b. MA Plan Enrollee Requirements and Burden

The following changes will be submitted to OMB for approval under control number 0938-NEW (CMS-10718). The control number for CMS-10718 has yet to be issued. The status of OMB's review/approval can be monitored at

https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202003-0938-002.

Section 422.514(e)(2) allows any individual transitioned from a D-SNP look-alike to another MA-PD plan to stay in the MA-PD plan receiving the enrollment or make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA-PD plan or receiving services through the original Medicare fee-for-service program option and enrollment in a stand-alone Prescription Drug Plan (PDP). Because the enrollment transition process will be effective on January 1 and notices would be provided during the AEP, affected individuals have opportunities to make different plan selections through the AEP (prior to January 1) or the Medicare Advantage Open Enrollment Period (after January 1). Affected individuals may also qualify for a Special Election Period (SEP), such as the SEP for plan non-renewals at § 422.62(b)(1) or the SEP for dually eligible/LIS beneficiaries at § 423.38(c)(4).

Based on our experience with passive enrollment of dually eligible beneficiaries into a new plan under the same parent organization for MMPs in the Financial Alignment Initiative, we estimate that one percent of the 180,758 transitioning D-SNP look-alike enrollees will select a

new plan or the original Medicare fee-for-service program and PDP option rather than accepting the transition into a different MA-PD plan or D-SNP under the same MA organization as the D-SNP look-alike in which they are currently enrolled. We estimate that 1,808 enrollees ($180,758 \text{ transitioning D-SNP look-alike enrollees} * 0.01$), will opt out of the new plan into which the D-SNP look-alike transitioned them. Consistent with the burden estimates under the aforementioned control number, the enrollment process requires 20 minutes (0.3333 hours) and remains unchanged. For this final rule, the total added burden for enrollees will be 603 hours ($1,808 \text{ enrollees} * 0.3333 \text{ hr/response}$) at a cost of \$15,509 ($603 \text{ hr} * \$25.72/\text{hr}$). We are averaging this burden over the 2021 and 2022 plan years, resulting in an annual burden of 302 hours ($603 \text{ hr}/2 \text{ yr}$) at a cost of \$7,755 ($\$15,509/2 \text{ yr}$).

As stated previously, we believe that in subsequent years (2023 and beyond), at most five plans will be identified as D-SNP look-alikes and therefore this final regulation would have a much smaller impact on MA enrollees after the initial period of implementation. Since the current 62 D-SNP look-alike plans have 180,758 enrollees in 62 plans, we estimate 14,577 enrollees ($180,758 \text{ enrollees} * 5/62 \text{ plans}$) in 5 plans. Therefore, the maximum number of enrollees affected per year is estimated to be 146 enrollees ($14,577 \text{ total enrollees estimated in five plans} * 0.01 \text{ who would select another plan}$). This would amount to a maximum annual burden of 49 hours ($146 \text{ enrollees} * 0.3333 \text{ hr}$) at a cost of \$1,260 ($49 \text{ hr} * \$25.72/\text{hr}$).

The average annual enrollee burden over three years is therefore 218 hours ($[(302 \text{ hr} + 302 \text{ hr} + 49 \text{ hr})/3 \text{ yr}]$) at a cost of \$5,590 ($[\$7,755 + \$7,755 + \$1,260]/3\text{yr}$). The estimates are summarized in Table 4.

c. Burden Summary

The burden for the provisions are summarized in Table 4.

TABLE 4: SUMMARY OF BURDEN ESTIMATES FOR CONTRACT REQUIREMENTS AT § 422.514

Respondents	Subject	OMB Control No. (CMS ID No.)	2021	2022	2023	3-year average
MA organization	Transition enrollees (§ 422.514(e))	0938-0753 (CMS-R-267)	\$4,783 (62 hr)	\$4,783 (62 hr)	\$771 (10 hr)	\$3,446 (45 hr)
Beneficiaries	Enrollment request (§ 422.514(e))	0938-NEW (CMS-10718)	\$7,755 (302 hr)	\$7,755 (302 hr)	\$1,260 (49 hr)	\$5,590 (218 hr)
TOTAL			\$12,538 (364 hr)	\$12,538 (364 hr)	\$2,031 (59 hr)	\$9,036 (263 hr)

3. ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

As discussed in section III.A. of this final rule, we are revising §§ 422.50(a)(2), 422.52(c), and 422.110(b) to allow ESRD beneficiaries, without any limitation not otherwise applicable for enrollment in the MA program to enroll in an MA plan. In estimating the impact of this provision, we are required to separately estimate impact on beneficiaries and plans. Enrollment processing and notification requirements codified at § 422.60, are not being revised as part of this rulemaking, and no new or additional information collection requirements are being imposed.

Additionally, as explained in section VIII.D.1 of this final rule, OACT has already incorporated an increase in ESRD enrollment in the Medicare Trust Fund baseline due to the legislation. Therefore, there is no need to estimate plan burden. However, the burden to enrollees for completing enrollment forms has not been incorporated into the OACT baseline and therefore is estimated later in this section.

We did not receive any public comments on our proposed requirements. In the proposed rule, beneficiary burden was estimated using the “long” enrollment form that is currently

approved by OMB under control number 0938-0753 (CMS-R-267). Based on internal review, in this final rule, the beneficiaries will instead, be completing a new, “shortened” form (OMB control number 0938-NEW (CMS-10718)) for enrollment into MA plans beginning with the 2020 AEP, for a January 1, 2021 effective date. The new “shortened” enrollment form , which is three pages in length, (compared to the current model form which is seven pages), limits the data collection to the minimum that is lawfully required to process the enrollment and other limited information that the sponsor is required to, or chooses to, provide to the beneficiary.

As indicated in the beginning of this section, the shortened form has been subject to the standard non-rule PRA process (see 84 FR 63655 (November 18, 2019), 84 FR 64319 (November 21, 2019), and 85 FR 13163 (March 6, 2020)) and is currently under OMB review.

In this final rule, we are correcting our proposed beneficiary burden estimates by considering the completion of the shortened enrollment form (CMS-10718) in lieu of (CMS-R-267). As indicated in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

To elect a MA plan, an individual must complete and sign an election form, complete another CMS-approved election method offered by the MA plan, or call 1-800-MEDICARE, and provide information required for enrollment. Regardless of the enrollment mechanism, similar identifying information is collected by the MA plan to process the enrollment.

Although not effective until January 1, 2021, section 17006 of the Cures Act amends the Act by allowing ESRD beneficiaries, without any limitation not otherwise applicable for enrollment in the MA program, to enroll in an MA plan. The burden is associated with the effort for an ESRD beneficiary seeking to enroll in a MA plan to complete an enrollment request. Because there will be an increase in the number of beneficiaries eligible to elect an MA plan

starting in plan year 2021, the number of beneficiaries who are expected to initiate an enrollment action will increase. However, the erroneous per response time estimate of 30 minutes (0.5 hr) (CMS-R-267) that was set out in our proposed rule will decrease to 20 minutes (0.3333 hr) per response based on beneficiary completion of the new, shortened enrollment form (CMS-10718)).

As detailed in section VIII.D.1. of this final rule, OACT estimates an average increase of 59,000 ESRD beneficiaries to enroll in MA plans per year in 2021 through 2023. Therefore, we expect an average annual burden of 19,665 hours (59,000 new ESRD enrollees * 0.3333 hr) at a cost of \$505,784 (19665 hr * \$ 25.72/hr).

4. ICRs Regarding Medical Loss Ratio (MLR) (§ 422.2440)

MSA Enrollment

The anticipated changes affecting MSA enrollment will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267). Subject to renewal, the control number is currently set to expire on December 31, 2021. We did not receive any comments pertaining to our proposed requirements or burden estimates. However, based on internal review, we have updated our proposed time to complete the enrollment form and adjusted (increased) our enrollment figures to better reflect implementation in 2022 - 2024. As indicated above in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

As discussed in section IV.D.4. of this rule, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor would serve as a multiplier on the credibility factor. The application of the deductible factor would increase the MLRs of MSA contracts that receive this adjustment.

We believe that the change to the MLR calculation for MSAs could potentially cause the number of enrollees in MSA plans to increase relative to enrollment projections under the current regulations because we expect more MA organizations to offer MA MSA plans based on this change in the MLR calculation. Consistent with the proposed rule, for this impact estimate, we assume the following:

- Enrollment in MSAs will double over the first 3 years that the change is in effect. We believe 3 years is a reasonable time frame for the enrollment changes resulting from this policy to be phased in. We project that enrollment will double in order to avoid potentially understating the cost for the proposal. Our estimate is based on the largest potential change in enrollment that we could reasonably anticipate. We acknowledge that the change could have no impact on enrollment.

- Relative to projections in the baseline, MSA enrollment will be 33.33 percent higher in contract year 2022 (increasing from 7,812 to 10,416), 66.67 percent higher in 2023 (increasing from 8,179 to 13,632), and 100 percent higher in contract year 2024 (increasing from 8,531 to 17,062) to contract year 2030 (increasing from 10,354 to 20,708).

- Half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare. We did not have a basis for assuming whether migration to MSAs would predominantly be from FFS Medicare or from non-MSA MA plans.

The process for enrolling in an MA plan is the same regardless of whether that plan is an MSA or a non-MSA. Therefore, we assume that the burden to enroll in an MSA plan and a non-MSA plan is the same. Therefore, the increased burden related to changes in MSA enrollment is attributable only to the portion of potential new MSA enrollees who would be

expected to enroll in (or remain in) FFS Medicare if the proposal were not finalized. The cost burden of the provision is summarized in Table 5.

a. Beneficiary Requirements and Burden

For beneficiaries, the burden associated with the expected increase in MSA enrollment as a consequence of the addition of a deductible factor to the MSA MLR calculation is related to the effort it takes for a beneficiary to complete an enrollment request. It takes 0.5 hours at \$25.72/hr for a beneficiary to complete an enrollment form. We assume no burden increase for the estimated 50 percent of additional MSA enrollees who would otherwise be enrolled in a non-MSA MA plan. For 2022, the burden for all beneficiaries is estimated at 434 hours (2,604/2 beneficiaries * 0.3333 hr) at a cost of \$11,162 (651 hr * \$25.72/hr). For 2023, the burden for all beneficiaries is estimated at 909 hours (5,453/2 beneficiaries * 0.3333 hr) at a cost of \$23,379 (1,302 hr * \$25.72/hr). For 2024, the burden for all beneficiaries is estimated at 1,422 hours (8,531/2 beneficiaries * 0.3333 hr) at a cost of \$36,574 (1,422 hr * \$25.72/hr).

The average burden per year is 922 hours $([434+909+1422]/3)$ at a cost of \$23,705 $([11162+23379+36574]/3)$

b. MA Organization Estimate

There are currently four MA organizations offering MSA plans in 2020. We project that this number will double in 2022 as a result of the change. We therefore estimate that the change would result in approximately 2,604 total additional enrollments in MSAs in 2022, or 326 additional enrollments per organization (2,604 individuals/8 organizations); in 2023, 5,453 total additional enrollments in MSAs, or 682 additional enrollments per organization (5,453 individuals/8 organizations); and in 2024, and 8,531 total additional enrollments, or 1,066 additional enrollments per organization (8,531 individuals/8 organizations).

An MA organization must give a beneficiary prompt written notice of acceptance or denial of the enrollment request in a format specified by CMS that meets the requirements set forth in this section. The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. We estimate that it will take 1 minute at \$77.14/hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each beneficiary. As noted previously, we anticipate that half of the new enrollees in MSAs will already be enrolled in other MA plans, meaning the current burden estimate for their enrollment is already accounted for in the currently approved collection.

For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours (2,604/2 notices * 1 min/60) at a cost of \$1,697 (22 hr * \$77.14/hr) or \$1.30 per notice (\$1,697/1,302 notices) or \$212 per organization (\$1,697/8 MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 45 hours (5,453/2 notices * 1 min/60) at a cost of \$3,471 (45 hr * \$77.14/hr) or \$1.28 per notice (\$3,471/2,727 notices) or \$434 per organization (\$3,471/8 MA organizations). For 2024, the burden is approximately 71 hours (8,531/2 notices * 1 min/60) at a cost of \$5,477 (71 hr * \$77.14/hr) or \$1.134 per notice (\$5,470/4,090 notices) or \$685 per organization (\$5,246/8 MA organizations).

The average burden per year is 46 hours $([22 \text{ hr} + 45 \text{ hr} + 71 \text{ hr}]/3)$ at an average cost of \$3,548 $([\$1,697 + \$3,471 + \$5,477]/3)$.

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at \$77.14/hr for a business operations specialist to submit the enrollment

information to CMS during the open enrollment period. For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours ($2,604/2$ notices * 1 min/60) at a cost of \$1,697 ($22 \text{ hr} * \$77.14/\text{hr}$) or \$1.30 per notice ($\$1,697/1,302$ notices) or \$212 per organization ($\$1,697/8$ MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 45 hours ($5,453/2$ notices * 1 min/60) at a cost of \$3,471 ($45 \text{ hr} * \$77.14/\text{hr}$) or \$1.28 per notice ($\$3,471/2,727$ notices) or \$434 per organization ($\$3,471/8$ MA organizations). For 2024, the burden is approximately 71 hours ($8,531/2$ notices * 1 min/60) at a cost of \$5,477 ($71 \text{ hr} * \$77.14/\text{hr}$) or \$1.33 per notice ($\$5,477/4,090$ notices) or \$685 per organization ($\$5,477/8$ MA organizations).

The average burden per year is 46 hours ($[22 \text{ hr} + 45 \text{ hr} + 71 \text{ hr}]/3$) at an average cost of \$3,548 ($[\$1,697 + \$3,471 + \$5,477]/3$).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at \$36.82/hr for an office and administrative support worker to perform record retention for the additional MA MSA enrollees.

In aggregate, we estimate an annual burden for 2022 of 109 hours ($2,604/2$ beneficiaries * 5 min/60) at a cost of approximately \$4,013 ($109 \text{ hr} * \$36.82/\text{hr}$) or \$502 per organization ($\$4,013/8$ MA organizations). For 2023, we estimate an aggregated annual burden of 227 hours ($5,453/2$ beneficiaries * 5 min/60) at a cost of approximately \$8,358 ($227 \text{ hr} * \$36.82/\text{hr}$) or \$1,634 per organization ($\$7,821/8$ MA organizations). For 2024, we estimate an aggregated annual burden of 355 hours ($8,531/2$ beneficiaries * 5 min/60) at a cost of approximately \$13,071 ($355 \text{ hr} * \$36.82/\text{hr}$) or \$1,634 per organization ($\$13,071/8$ MA organizations).

The average burden per year is 230 hours ($[109 \text{ hr} + 227 \text{ hr} + 355 \text{ hr}]/3$) at an average cost of \$8,481 ($[\$4,013 + \$8,358 + \$13,071]/3$).

MLR Calculation

The changes affecting the MLR calculation will be submitted to OMB for approval under control number 0938-1232 (CMS-10476). Subject to renewal, the control number is currently set to expire on December 31, 2021.

We did not receive any public comments on our proposed requirements or burden estimates. We are finalizing the requirements as proposed. We are also finalizing the burden estimates, with the following revisions: (1) we updated our cost figures using more recent BLS wage estimates; (2) we reduced the hour burden for an enrollee to fill out an enrollment form; and (3) we adjusted the 3-year phase-in period for the anticipated enrollment changes from 2021 to 2023 in the proposed rule to 2022 to 2024 in this final rule.

MA organizations will need to spend additional time calculating the MLRs for MSA contracts in order to apply the deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2022 and in each year through 2030, it will take an actuary approximately 5 minutes (0.0833 hr) at \$116.32/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.6664 hours ($0.0833 \text{ hr} * 8 \text{ MA organizations}$) at a cost of \$78 ($0.6664 \text{ hr} * \$116.32/\text{hr}$) or \$10 per organization ($\$78 / 8 \text{ organizations}$).

For 2022, we estimate a total burden for all MA organizations resulting from this provision to be 154 hours ($22 \text{ hr} + 22 \text{ hr} + 109 \text{ hr} + 0.6664 \text{ hr}$) at a cost of \$7,485 ($\$1,697 + \$1,697 + \$4,013 + \78). Per organization, we estimate an annual burden of 19.3 hours ($154 \text{ hr}/8 \text{ MA organizations}$) at a cost of \$935.63 ($\$7,485/8 \text{ organizations}$).

For 2022, we estimate a total burden for all MA organizations resulting from this provision to be 154 hours (22 hr + 22 hr + 109 hr + 0.6664 hr) at a cost of \$7,485 (\$1,697 + \$1,697 + \$4,013 + \$78). Per organization, we estimate an annual burden of 19.3 hours (154 hr/8 MA organizations) at a cost of \$935.63 (\$7,485/8 organizations).

For 2023, we estimate a total burden for all MA organizations resulting from this provision to be 318 hours (45 hr + 45 hr + 227 hr + 0.6664 hr) at a cost of \$15,378 (\$3,471 + \$3,471 + \$8,358 + \$78). Per organization, we estimate an annual burden of approximately 40 hours (318 hr/8 MA organizations) at a cost of \$1,922.50 (\$15,378/8 organizations).

For 2024, we estimate a total burden for all MA organizations resulting from this provision to be 498 hours (71 hr + 71 hr + 355 hr + 0.6664 hr) at a cost of \$24,103 (\$5,477 + \$5,477 + \$13,071 + \$78). Per organization, we estimate an annual burden of approximately 62 hours (498 hr/8 MA organizations) at a cost of \$3,013 (\$24,103 /8 organizations).

The burden for beneficiaries is a single burden for each year and has been estimated above.

d. Summary

The figures in Table 5 associated with beneficiaries' enrollment requests, MA organizations providing beneficiaries with notice of acceptance or denial of the enrollment request, MA organizations' submission of enrollment information to CMS, and MA organizations' retention of a copy of the notice in beneficiaries' records will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267). The figures associated with the calculation of the deductible factor for MA MSA contracts will be submitted to OMB for approval under control number 0938-1232 (CMS-10476).

TABLE 5: IMPACT OF MSA/MLR BY SUBJECT

Respondents	Subject	OMB Control No. (CMS ID No.)	2022	2023	2024	Average
Beneficiaries	Enrollment request (§ 422.2440)	0938-0753 (CMS-R-267)	\$11,162 (434 hr)	\$23,379 (909 hr)	\$36,574 (1,422 hr)	\$23,705 (922 hr)
MA organizations	Notice to beneficiaries (§ 422.2440)	0938-0753 (CMS-R-267)	\$1,697 (22 hr)	\$3,471 (45 hr)	\$5,477 (71 hr)	\$3,548 (46 hr)
MA organizations	Submission to CMS (§ 422.2440)	0938-0753 (CMS-R-267)	\$1,697 (22 hr)	\$3,471 (45 hr)	\$5,477 (71 hours)	\$3,548 (46 hrs)\$
MA organizations	Record retention (§ 422.2440)	0938-0753 (CMS-R-267)	\$4,013 (109 hr)	\$8,358 (227 hr)	\$13,071 (355 hr)	\$8,481 (230 hr)
MA organizations	Calculation of deductible factor (§ 422.2440)	0938-1232 (CMS-10476)	\$78 (0.6664 hr)	\$78 (0.6664 hr)	\$78 (0.6664 hr)	\$78 (0.6664 hr)
TOTAL			\$7,485 (154 hr)	\$15,378 (318 hr)	\$24,103 (498 hr)	\$15,655 (322 hr)

5. ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

The following changes will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267) for Part C and 0938-0964 (CMS-10141) for Part D.

As discussed in section V.B. of this final rule, we are finalizing all SEPs as proposed, with the exception of the SEP for Government Entity-Declared Disaster or Other Emergency at §§422.68(b)(18) and 423.38(c)(23), which we are finalizing, with modification. We are also codifying the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B, which was inadvertently omitted from the proposed rule.

We did not receive any comments on our proposed requirements and are finalizing them without change. As indicated in section VII.A. of this final rule, we have revised our proposed cost figures based on more recent BLS wage estimates. We are not making any changes to our proposed time estimates.

We are codifying certain Part C (at § 422.62(b)(4) through (25)) and Part D (at § 423.38(c)(11) through (32)) SEPs for exceptional circumstances currently set out in sub-

regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also establishing two new additional SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We do not believe the changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the changes would have any impact on the Medicare Trust Fund.

MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this change. However, because the burden for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under the aforementioned OMB control numbers.

The following changes will be submitted to OMB for approval under control number 0938-0753 (CMS-R-267). We estimate it would take 5 minutes (0.0833 hr) at \$77.14/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections * 0.0833 hr) at a cost of \$10,992,219 (142,497 hr * \$77.14/hr) or \$60,731 per parent organization (\$10,992,219/181 MA parent organizations).

The following changes will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 0.0833 hr) at a cost of \$12,000,207 (155,564 hr * \$77.14/hr) or \$226,419 per Part D parent organization (\$12,000,207/53 Part D parent organizations).

As discussed in section V.B. of this final rule, we are finalizing all SEPs as proposed, with the exception of the SEP for Government Entity-Declared Disaster or Other Emergency at §§ 422.68(b)(18) and 423.38(c)(23). We are also codifying the SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B, which was inadvertently omitted from the proposed rule.

C. Summary of Information Collection Requirements and Associated Burden Estimate

TABLE 6: ANNUAL INFORMATION COLLECTION REQUIREMENTS

Provision	Regulatory Citation	OMB Control Number	Respondent type	Response Summary	Total Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Annual Time (hr.)	Labor Cost (\$/hr)	Total Annual Cost (\$)
D-SNP Look-Alikes	§ 422.514 (e)	0938-NEW	Enrollees	D-SNP Look-Alikes: Enrollment	1,954	1,954	0.3333	218	25.72	5,590
ESRD	§§ 422.50 and 422.52	0938-NEW	Enrollees	ESRD: Enrollment	59,000	59,000	0.3333	19,665	25.72	505,784
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Enrollees	MSA MLR: Filling out enrollment forms	16,588	16,588	0.3333	922	25.72	23,705
	Subtotal Enrollees	Varies	Enrollees	Varies	77,542	77,542	varies	20,805	Varies	535,079
SSCBI	422.102(f)(3)(i)	0938-0763	MA Plans	SSBCI: Criteria (initial software update)	234	1	12	2808	103.33	96,717
SSCBI	422.102(f)(3)(i)	0938-0763	MA Plans	SSBCI: Criteria (Annual physician review)	234	1	36	8424	193.7	1,631,729
SSCBI	422.102(f)(3)(i)	0938-0763	MA Plans	SSBCI: Criteria (Software updates)	234	1	5	1170	85.26	99,754
SSCBI	422.102(f)(3)(ii)	0938-0763	MA Plans	SSBCI: Documentation	234	1	2	468	56.34	26,367
SSCBI	422.102(f)(3)(iii)	0938-0763	MA Plans	SSBCI: Enrollee records	234	1	9	702	86.95	61,039
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	MA Plans	D-SNP Look-Alikes: Transition	67	67	2	45	77.14	3,446

MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	MA Plans	MSA MLR: Notify enrollees	8	8	0.0167	46	77.14	3,548
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	MA Plans	MSA MLR: Submit to CMS	8	8	0.0167	46	77.14	3,548
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	MA Plans	MSA MLR: Archive	8	8	0.0833	230	36.82	8,481
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-1252	MA Plans	MSA MLR: Calculation of the deductible factor	8	8	0.0833	0.6664	116.32	78
Part C Election Period	§ 422.62	0938-0753	MA Plans	Part C Election Period: Determine eligibility	181	1,710,650	0.0833	142,497	77.14	10,992,219
Part D Election Period	§ 422.38	0938-0964	Part D Plans	Part D Election Period: Determine eligibility	53	1,867,519	0.0833	155,564	77.14	12,000,207
	Subtotal MA Plans	Varies	Ma Plans	Varies	309	Varies	Varies	312,001	Varies	24927133
	Grand Total All	Varies	Varies	Varies	77,851			332,806		\$25,462,212

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule implements a subset of the proposals from the proposed rule. We took a measured approach to review each provision proposed and focused finalizing in this first final rule those most helpful for bidding, those that address the COVID-19 pandemic and public health emergency, as well as those topics on which issuing a final rule now would advance the MA program.

Summaries of the public comments that are within the scope of the provisions' proposed regulatory impact analyses implemented in this final rule are included in this section with our responses under the appropriate headings. The provisions in this final rule implement specific provisions of the BBA of 2018 and the 21st Century Cures Act. The statutory need for these policies is clear. However, this rule also contains discretionary policies, hence we provide economic justification in the following paragraphs.

We estimate that the proposed Star Ratings provisions would result in an overall net savings for the Medicare Trust Fund. There are two changes that may impact a contract's Star Rating: (1) we proposed to increase measure weights for patient experience/complaints and access measures from two to four to further emphasize the patient voice, and (2) we proposed the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the non-CAHPS measure cut points. The increased weight reflects CMS's commitment to put patients first and to empower patients to work with their doctors to make health care decisions that are best for them. Since more outliers tend to be at the low end of the distribution (worse performers), directly removing outliers causes some shifting downward in overall Star Ratings. The increased measure weights for patient

experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund given the ratings for these measures tend to be higher relative to other measures, and the Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund after the first year since directly removing outliers results in a shift downward in ratings. The aggregate savings to the Medicare Trust Fund over 2024-2030 is \$4.1 billion.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This rule, under Executive Order 12866, is economically significant with over \$100 million in costs, benefits, or transfers annually. Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a major rule as defined by 5 U.S.C. 804(2).

A regulatory impact analysis must be made for major rules with economically significant effects (\$100 million or more in any one year). We estimate that this final rule is economically significant as measured by the \$100 million threshold and hence, it is also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of this rulemaking.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This final rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA-PD, and PDP contracts), 55 state Medicaid agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11-9111), we estimate that the cost of reviewing this final rule is \$110.74 per hour, including fringe benefits and overhead costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 100 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore \$11,074 (100 hours * \$110.74). Therefore, we estimate that the maximum total cost of reviewing this final

rule is \$22 million (\$11,074* 2,000 reviewers). We expect that many reviewers will not review the entire rule but just the sections that are relevant to them. If each person on average reviews 10 percent of the rule, then the cost would be \$2.2 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

C. Impact on Small Businesses – Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule has several provisions. Although some provisions are technical or codify existing guidance, and therefore are not expected to have economic impact beyond current operating expenses, there are other provisions with paperwork or other costs. These provisions are analyzed in both this section and in section VII of this final rule. A compact summary of burdens by year and provision are summarized in Tables 6 and 16 of this final rule.

This rule has several affected stakeholders. They include (1) insurance companies, including the five types of Medicare health plans, MA organizations, PDPs, cost plans, Medical Savings Account plans (MSA), PACE organizations, and demonstration projects, (2) providers,

including institutional providers, outpatient providers, clinical laboratories, and pharmacies, and (3) enrollees.

Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a \$30 million threshold for “small size” with 88 percent of pharmacies, those with less than 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a \$41.5 million threshold for “small size,” with 75 percent of insurers having under 500 employees meeting the definition of small business.
- Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from \$8 to \$35 million (Dialysis Centers, NAICD 621492, have a \$41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed \$34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals have a \$41.5 million threshold for small size, with half of the hospitals (those with between 20-500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a \$30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this final rule does not have a significant economic impact on a substantial number of small entities. To defend our position, we first describe at a high level the cash flows related to the Medicare program. We then provide more specific details.

The high-level underlying idea in creating the MA, Medicare Cost-plan, and MA-PD Medicare health insurance programs, is to allow private insurers to coordinate care, resulting in efficiencies of cost. The high-level underlying idea in creating the non-government-managed Prescription Drug program (PDPs and drug portion of MA-PDs) is to allow beneficiaries to obtain prescription drugs in a competitive market to reduce costs. For MA, MA-PD and Cost plans, enrollees obtain the same Original Medicare Part A and Part B services they would otherwise obtain in the original Medicare program, albeit at reduced cost (however, for the small percentage of plans bidding above the benchmark, enrollees pay more, but this percentage of plans is not “significant” as defined by the RFA and as justified below).

The savings achieved by the MA and the MA-PD plans, the amount of reduced cost, can then be used by the private insurers in a variety of ways, including providing benefits supplemental to original Medicare. Some examples of these supplemental benefits include vision, dental, and hearing. The cost for furnishing these supplemental benefits comes from a combination of the Trust Fund and enrollee premiums.

Part D plans submit bids and are paid by the Medicare Trust Fund for their projected costs in the form of direct premium subsidy and reinsurance. For any enrolled low-income beneficiaries, they receive low-income premium subsidy and low-income cost-sharing subsidy in addition. The national average monthly bid amount, or NAMBA, determines the base premium. A plan’s premium is the sum of the base premium and the difference between its bid amount and the NAMBA.

Thus the cost of providing services by these insurers is met by a variety of government funding and in some cases by enrollee premiums.

In order to achieve these goals, the government pays the MA health plans a portion of the funds that would have been paid had plan enrollees remained in original Medicare. These funds are then used to provide additional benefits on behalf of the health plans' enrollees. Thus, by the initial design of the Medicare health plan programs, the various insurance programs were not expected to suffer burden or losses since, in this very unique insurance relationship, the private companies are being supported by the government who, in turn, is saving money because health plans, by virtue of coordinating care, are furnishing the same services, albeit at reduced cost. This lack of expected burden applies to both large and small health plans.

The unique MA regulations, such as those in this final rule, are defined so that small entities are not expected to incur additional burden since the cost of complying with any final rule is passed on to the government.

We next examine in detail each of the stakeholders and explain how they can bear cost. (1) For Pharmacies and Drug Stores, NAICS 446110; (2) for Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) for Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) for SNFs, NAICS 623110: Each of these are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs, PFFS, and MSA, non-contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 requires that a non-contracted provider accept payment that is least what they would have been paid had the services been furnished in a fee-for-service setting. For

contracted providers, § 422.520 requires that the payment is governed by a contract which the provider and plan mutually agree to. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the coming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the government. However, the government additionally pays the plan a “beneficiary rebate” amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan’s quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost sharing, lower Part B or Part D premiums, or supplemental

benefits. (Supplemental benefits may also partially be paid by enrollee premiums if the plan chooses to use premiums.) It would follow that if the provisions of this final rule cause the bid to increase and if the benchmark remains unchanged or increases by less than the bid does, the result would be a reduced rebate and possibly fewer supplemental benefits for the health plans' enrollees.

However, supplemental benefits are only one approach to using the rebate. The experience of OACT at CMS is that from year to year plans prefer to reduce their administrative costs, including profit margins, rather than substantially change their benefit package. This is true due to marketing forces; a plan lowering supplemental benefits even one year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it is advantageous to the plan to temporarily reduce administrative costs, including margins, rather than reduce benefits.

We note that we do not have definitive data on this. That is, we can at most note the way administrative costs and supplemental benefits vary from year to year. The thought processes behind the plan are not reported. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.⁵⁴

Based on the above, we certify that this final rule does not have a significant economic impact on a substantial number of small entities.

Finally, we note that this rule has an impact on enrollees. While enrollees as a group do not constitute a "small business" as defined by the RFA, and hence the impact of this final rule on enrollees is not discussed in this section, throughout this final rule we have carefully noted the

⁵⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3893317/>

impact on enrollees. One major impact on enrollees as presented in section VII of this final rule is the estimated half hour burden at a cost of \$13 per enrollee for filling out enrollment forms. While the aggregate amount for all enrollees is several million, the per enrollee burden is not significant.

D. Anticipated Effects

Some provisions of this final rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section VII of this final rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section VII of this final rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 16 and the discussion afterwards.

1. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

We are codifying requirements under section 17006 of the Cures Act that, effective for the plan year beginning January 1, 2021, would remove the prohibition on beneficiaries with ESRD enrolling in an MA plan. Since we are codifying existing statute, there is no impact to

program expenditures. In order to estimate the impact of requirements under section 17006 of the Cures Act, a pre-statute baseline was used to estimate the impacts.

There are two primary assumptions that contribute to the regulatory impact analysis for this provision: (1) the increased number of beneficiaries with ESRD who choose to enroll in an MA health plan; and (2) the cost differential between MA and FFS for those enrollees with ESRD.

We are expecting that there will be an influx of beneficiaries switching from FFS to MA beginning on January 1, 2021 due to the provision. In 2019, there were 532,000 enrollees in ESRD status with Medicare Part A benefits as shown in the Medicare Enrollment Projections tables of the 2020 Rate Announcement. Of these, 401,000 enrollees were in the FFS program, which results in 131,000 in Private Health Plans. This equates to a private health penetration rate of about 25 percent. Absent the ESRD enrollment provision of the Cures Act, we project that ESRD enrollment in Private Health plans will grow to 144,000 in 2021, representing about 26 percent of the projected 2021 total ESRD population of 559,000. Based on an analysis by OACT, ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years, with half of the beneficiaries (41,500) enrolling during 2021.

Next, we determine the cost differential of the projected ESRD enrollees that are new to MA in 2021 due to the Cures Act. The cost differential between MA and FFS ESRD enrollees is attributed to the adjustment to MA risk scores for differences in diagnosis coding between MA and FFS beneficiaries. The Coding Intensity (Annual) was derived by examining historical risk score data and computing the differences between MA and FFS risk scores. Demographic

differences (age, gender factors) for enrollees have been separated and removed from risk score comparisons so that the final differences are considered health status differences.

Table 7 shows the cost for codifying section 17006 of the Cures Act, removing the prohibition for ESRD beneficiaries to enroll in MA plans. The United States Per Capita Cost (USPCC) amounts for Part A and Part B can be found in the 2020 Rate Announcement. The Gross Costs (before backing out the Part B premium portion) is calculated by multiplying the Additional MA ESRD Enrollment by the ESRD-USPCC rates, which are on a per member per month basis, multiplied by 12 (the number of months in a year) multiplied by the Composite Coding Intensity. The Net Cost is calculated by multiplying the Gross Costs by the Net of Part B Premium amount which averages between 85.6% and 84.9% from 2021 – 2030. The Net Costs range from \$23 million in contract year 2021 to \$440 million in contract year 2030.

TABLE 7: ESTIMATED COST PER YEAR (MILLIONS) TO THE MEDICARE TRUST FUND FOR REMOVING THE PROHIBITION FOR ESRD BENEFICIARIES TO ENROLL IN MA PLANS

Contract Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Additional MA ESRD Enrollment:	41,500	62,250	73,317	78,850	81,617	83,000	83,000	83,000	83,000	83,000
USPCC Pt A FFS (\$):	3,206	3,328	3,447	3,562	3,681	3,801	3,924	4,052	4,184	4,320
USPCC Pt B FFS (\$):	4,900	5,109	5,329	5,573	6,383	6,662	6,953	7,257	7,574	7,905
USPCC FFS (\$):	8,106	8,437	8,776	9,136	10,063	10,462	10,877	11,309	11,758	12,225
Coding Intensity (Annual):	0.65%	0.80%	0.79%	0.63%	0.46%	0.30%	0.14%	0.14%	0.13%	0.13%
Coding Intensity (Composite):	0.65%	1.46%	2.26%	2.90%	3.38%	3.69%	3.84%	3.98%	4.12%	4.25%

Gross Cost (\$ millions):	26	92	174	251	333	384	416	448	482	518
Net of Part B Premium:	85.60 %	85.60 %	85.50 %	85.40 %	85.30 %	85.20 %	85.00 %	84.90 %	84.90 %	84.90 %
Net Cost (\$ millions):	23	79	149	214	284	327	353	381	410	440

Because these increases are already included in the baseline, they are not included in Table 15, nor do they contribute to the monetized table calculations (Table 15). However, notes to Table 15 and observations in the conclusion do mention this impact.

Comment: A commenter thanked CMS for sharing its projection of the magnitude of ESRD migration from Original Medicare to Medicare Advantage in 2021 and in future years; however, the commenter expressed several concerns with the methods and assumptions used. For example, the commenter requested CMS i) produce a range of impacts, ii) produce an alternative methodology based on adjustment to MOOP limits, and iii-iv) reconsider certain assumptions about MLR and migration patterns. The commenter also asked if CMS, in considering migration patterns, took note that many ESRD retirees are already in EGWPs or that migration to MA plans will likely be higher in the under-65 ESRD population due to the lack of alternatives.

Response: A range of impacts for the estimated costs to the Medicare Trust Funds for removing the prohibition for ESRD beneficiaries to enroll in MA plans is described in section VIII.E.1. of this final rule.

CMS does not have the information readily available to produce an alternative adjustment to MOOPs; the proposal related to the MOOP limits for MA plans will be addressed in a future final rule. The cost to the plan sponsor of having a MOOP is captured as a supplemental benefit in the bid pricing. The plan sponsor bid pricing models and methodologies are proprietary health

plan information and are not readily available to CMS. Furthermore, the MOOP for 2021 applies to all MA enrollees (ESRD and non-ESRD) and we do not believe it is reasonable to project alternative ESRD enrollment projections based on a MOOP that applies to all MA enrollees.

We did consider the migration patterns for EGWP ESRD beneficiaries versus Individual ESRD beneficiaries. We surmised that the costs differences between EGWP and Individual ESRD coverages are not significant enough to display the migration patterns separately. Displaying projections at that coverage level would not provide further understanding of the financial projections since the cost differences are not too different.

We did consider the migration patterns for younger versus older ESRD beneficiaries. In response to the commenter on page G24, we noted that the higher average age of the MA ESRD enrollee versus the lower average age of the FFS ESRD enrollee is a main reason that there are fewer kidney transplants in the MA population. Our expectation is that younger ESRD beneficiaries will begin to enroll in MA starting in 2021 and that the kidney transplant incidence rate for the two programs will begin to merge.

After review and consideration of the comments, we are finalizing this provision without modification.

2. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322) and Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853(k) and (n) of the Act to exclude standardized costs for kidney acquisitions from MA benchmarks starting in 2021. As such, we will codify these requirements so that, effective for the contract year beginning January 1, 2021, MA organizations will no longer be responsible for costs for organ acquisitions for kidney

transplants for their beneficiaries. Removing these costs from the MA benchmarks will decrease the amounts paid to the plans from the Medicare trust funds. Instead, as required by statute, Medicare FFS will cover the kidney acquisition costs for MA beneficiaries, effective 2021.

Since the budget baseline has reflected this change from the Cures Act, there is no additional impact of the proposed codification of this change to the computation of rates. To estimate the impact of the statute when published we used a pre-statute baseline. This impact of the statute will therefore not be included in Table 15 or Table 14, which deal with impacts of current provision.

Our analysis in the next section shows that: (1) FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from \$212 million in 2021 to \$981 million in 2030; (2) Excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from \$594 million in 2021 to \$1,346 million in 2030. In addition, we anticipate no change in plan, provider, or beneficiary burden for these provisions. Plan burden would not be impacted by the change in their payment rate. Provider burden will not be impacted because they continue to bill for kidney acquisition regardless of whether they receive payment from FFS Medicare or MA organizations. Finally, beneficiaries would not be impacted by the change in the source of payment for the acquisition of the organ.

Next, we describe the steps used to calculate the savings associated with excluding kidney acquisition costs from MA benchmarks as well as the costs associated with requiring FFS coverage of kidney acquisition costs for MA beneficiaries.

First, we examined the FFS cost of kidney acquisition coverage. We calculate the expected costs to the FFS program for covering kidney acquisitions from the MA population

starting in 2021. The costs for these services are expected to be lower than the amount that is expected to be excluded from the MA benchmarks for two reasons.

- The MA penetration rate for ESRD enrollees is lower than for the non-ESRD enrollees. This means that a higher percentage of beneficiaries with ESRD are in FFS than in MA, so there will likely be fewer kidney transplants in MA versus FFS. However, this enrollment difference will likely lessen as ESRD enrollees are permitted to enroll in MA plans beginning in 2021.

- The kidney transplant incidence rate for MA ESRD enrollees has historically been much lower than the kidney transplant incidence rate for FFS ESRD enrollees. We suspect that this is due to MA ESRD enrollees being in dialysis status for a shorter duration than FFS enrollees. Again, we believe that this difference (between MA and FFS) in the kidney transplant incidence rate will decrease over time as more ESRD beneficiaries enroll in MA plans.

The kidney transplant incidence rate is computed by dividing the number of kidney transplants by the ESRD enrollment separately for the MA and FFS programs. As shown in Table 8, the FFS kidney transplant incidence rate has historically often been more than three times the MA rate.

TABLE 8: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2013-2017)

	2013	2014	2015	2016	2017
Number of Kidney Transplants FFS:	13,964	13,866	14,400	15,191	15,346
ESRD Enrollment FFS (000's):	385	390	394	401	402
Transplant Incidence FFS:	3.6%	3.6%	3.7%	3.8%	3.8%
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Number of Kidney Transplants MA:	929	1,015	957	1,137	1,382
ESRD Enrollment MA (000's):	69	78	89	96	108
Transplant Incidence MA:	1.3%	1.3%	1.1%	1.2%	1.3%

As mentioned, we expect that as a greater portion of enrollees with ESRD will join MA plans, starting in 2021, the difference in the kidney transplant incidence rate between MA and FFS will begin to lessen, as shown in Table 9. The total number of MA and FFS kidney transplants are expected to grow by 3 percent per year which is based on the 2013 – 2017 historical growth rate. That rate is higher than the average increase in MA and FFS ESRD enrollment of 2 percent for 2013 – 2017. Since the kidney transplant growth is projected to be higher than the ESRD enrollment growth, we expect the kidney transplant incidence rate to increase over time.

TABLE 9: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2018-2030)

	2018	2019	2020	2021	2022	2023	2024
Number of Kidney Transplants MA & FFS:	17,230	17,747	18,279	18,828	19,392	19,974	20,573
Kidney Transplant Incidence FFS:	3.9%	4.0%	4.0%	4.2%	4.3%	4.4%	4.3%
Kidney Transplant Incidence MA:	1.4%	1.4%	1.4%	1.6%	1.8%	2.0%	2.2%
ESRD Enrollment FFS (000's):	401	401	408	373	358	353	352
ESRD Enrollment MA (000's):	120	131	137	186	213	231	242
	2025	2026	2027	2028	2029	2030	
Number of Kidney Transplants MA & FFS:	21,191	21,826	22,481	23,155	23,850	24,566	
Kidney Transplant Incidence FFS:	4.3%	4.2%	4.2%	4.1%	4.1%	4.0%	
Kidney Transplant Incidence MA:	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%	
ESRD Enrollment FFS (000's):	354	358	364	369	374	379	
ESRD Enrollment MA (000's):	250	256	261	266	270	274	

Then we calculate the average kidney acquisition costs using FFS claims data from CMS data systems. The average kidney acquisition costs ranged from \$69,000 in 2013 to \$83,000 in 2017, which equates to an annual growth rate of 4.7 percent. This percentage was used to estimate average kidney acquisition costs during the projection period of 2018 to 2030.

The gross costs to the FFS program for covering MA kidney acquisition costs are computed by multiplying the MA transplant incidence rate by the number of MA ESRD enrollees multiplied by the average kidney acquisition cost. This computation was completed for the years 2021 – 2030. The gross costs, as found in the Table 10, range from \$298 million in 2021 to \$1,384 million in 2030. Again, we apply the government share of the gross savings factors as well as the Part B premium factors to compute the net costs to the Medicare Trust Funds. These factors are the same as those used to calculate the savings for excluding kidney acquisition costs from the MA benchmarks. The net costs to the Medicare Trust Funds after applying these factors are expected range from \$212 million in 2021 to \$981 million in 2030.

TABLE 10: COSTS TO THE FFS PROGRAM FOR COVERING MA KIDNEY ACQUISITION COSTS

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021-2030
Kidney Transplant Incidence MA:	1.6%	1.8%	2.0%	2.2%	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%	--
ESRD Enrollment MA (000's):	186	213	231	242	250	256	261	266	270	274	--
Avg Kidney Acq Costs (\$'s):	99,146	103,804	108,680	113,786	119,131	124,728	130,587	136,722	143,145	149,870	--
Gross Costs (\$Millions):	297.9	401.3	503.0	605.7	713.5	828.7	950.2	1,082.5	1,226.1	1,383.7	7,992.6
Avg Gov't Share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%	--
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%	--

Net Costs (\$Millions):	211.7	284.9	357.0	429.5	506.0	587.1	672.3	766.5	869.1	980.8	5,664. 9
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Next, we examined the MA cost of kidney acquisition coverage. We used data based on the kidney acquisition costs for the FFS beneficiaries to compute the portion of the MA benchmark that has been attributed to kidney acquisition costs. In order to compute the amount that the MA health plans have been reimbursed for these costs in the past, we tabulated Medicare’s share of kidney acquisition costs and the number of Medicare discharges from the Medicare Cost Reports (Form CMS-2552-10) for certified kidney transplant centers. The kidney acquisition costs were computed for the years 2013 – 2017 (the latest data that was available at the time of this study) using information from the Medicare Cost Reports for FFS beneficiaries at the county-level. The county level per member per month (PMPM) costs are derived by summing the kidney acquisition costs for each county and dividing these amounts by the county specific Medicare FFS enrollment. These annual costs per member are then divided by 12 in order to compute the PMPM’s.

Next, we examine the historical kidney acquisition cost PMPM trend for the years 2013 – 2017 to project these costs for the years 2018 – 2030. In aggregate, the kidney acquisition PMPM costs grew at an average rate of 6.4 percent during 2013 – 2017. This trend is used to estimate these costs for the 2018 – 2030 period.

To calculate the gross savings to the Medicare Trust Funds, we multiply the projected MA enrollment by the annual per member kidney acquisition costs. We then apply two additional factors to the gross savings in order to compute the net savings to the Medicare Trust Funds:

- Average government share of gross savings. Government expenditures are the sum of bids and rebates. Rebates are the portion of the difference between the MA benchmarks and MA bids that the health plans use to pay for additional supplemental benefits or reductions in enrollee cost sharing. The government retains the remaining difference between MA benchmarks and MA bids. We estimate that bids will be reduced by 50 percent of the total reduction in benchmarks.

- Net of Part B premium. Medicare enrollees, not the Trust Funds, are responsible for approximately 25 percent of their Part B costs.

The government share of gross savings factors are expected to be between 83.0 percent and 83.4 percent during the period 2021 – 2030. The net of Part B premium factors are expected to be 85.6 percent and 84.9 percent during that same period. The results can be found in Table 11. The net savings due to excluding kidney acquisition costs from MA benchmarks is estimated to range from \$594 million in 2021 to \$1,346 million in 2030.

**TABLE 11: PER-YEAR CALCULATIONS, REPRESENTING THE PRE-STATUTE BASELINE BASED ON MEDICARE
FFS COVERAGE OF KIDNEY ACQUISITION COST**

	2013	2014	2015	2016	2017	2018	2019	2020			
Kidney Acq Costs (PMPM):	1.72	1.82	1.95	2.08	2.20	2.34	2.49	2.65			
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021-2030
Kidney Acq Costs (PMPM):	2.82	3.00	3.20	3.40	3.62	3.85	4.10	4.36	4.64	4.94	--
Medicare Advantage Enrollment Projection (000's):	24,690	25,624	26,508	27,380	28,237	29,070	29,861	30,607	31,313	32,035	--
Gross Savings (\$Millions):	836.2	923.5	1,016.6	1,117.4	1,226.3	1,343.4	1,468.4	1,601.7	1,743.7	1,898.4	13,175.6
Average government share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%	--
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%	--
Net Savings (\$Millions):	594.1	655.7	721.5	792.3	869.5	951.7	1,038.9	1,134.1	1,235.9	1,345.6	9,339.3

Comment: A commenter expressed concern about the estimates in the regulatory impact analysis that concluded the net savings attributable to the exclusion of kidney acquisition costs from MA benchmarks exceed the net costs attributable to FFS coverage of kidney acquisition costs. The commenter also pointed to the Congressional Budget Office's November 2016 cost estimate of the Cures Act, which reported no change in federal spending, to underscore the notion that the net savings estimated in the proposed rule were not intended by the change in law.

Response: We thank the commenter for this feedback. Total MA kidney acquisition costs have historically been lower than total FFS kidney acquisition costs for two main reasons: (1) MA transplant incidence has been lower than FFS transplant incidence; and (2) MA ESRD enrollment (as a percent of total MA enrollment) has been lower than FFS ESRD enrollment (as a percent of total FFS enrollment). These factors result in a lower number of MA kidney transplants per capita versus FFS kidney transplants per capita. We expect savings from the exclusion of kidney acquisition costs from the MA benchmarks since MA plans have historically been reimbursed for these costs based on the higher rate of transplantation in FFS. We believe our impact analysis sufficiently outlined why the shift in responsibility from MA to FFS is not budget neutral.

Comment: Some commenters requested that we explain why the estimates in the 2021 Advance Notice appear to diverge from the estimates included in the proposed rule. The commenters indicated that the FFS cost of kidney acquisition would be an estimated \$2.82 PMPM while the Advance Notice indicated that the carve-out impact estimate would be \$4 PMPM.

Response: The Medicare FFS cost of kidney acquisitions estimate provided in the proposed rule is a national estimate of the impact on the Medicare Trust Funds. In contrast, the

preliminary estimate provided in the calendar year 2021 Advance Notice represents a county-level average impact of excluding kidney acquisition costs from FFS experience on the MA non-ESRD county rates. Additionally, the estimates provided in the proposed rule and the Advance Notice were calculated using different trending assumptions and underlying data. The updated estimate of the impact figure that was provided in the calendar year 2021 Advance Notice is \$3.

Comment: A few commenters questioned the credibility of county level data in determining the kidney acquisition cost carve-out amounts and requested that CMS release the supporting data and analyses. A commenter specifically pointed to Tables 26 and 27 in the proposed rule, noting that there were approximately 75,000 kidney transplants paid by FFS during 2014-2018 (the data period used to compute the kidney acquisition carve-out amounts). The commenter expressed concern regarding the credibility of using 75,000 events to develop 3,225 county specific carve-out factors, and requested that the kidney acquisition cost factors be developed across broader geographic areas than counties in order to mitigate variability and potential credibility issues that may exist when forecasting county level carve-out amounts.

Response: CMS provided a step-by-step description of the methodology for calculating the kidney acquisition costs to be excluded from the MA benchmarks on pages 25 and 26 of the calendar year 2021 Advance Notice.⁵⁵ Consistent with the statutory requirement to exclude the cost of kidney acquisitions for organ transplants from the primary components of the MA capitation rates, CMS finalized the kidney acquisition carve-out methodology after considering all public comments received.

⁵⁵ The Advance Notice and Rate Announcement for each year are available online at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents>

Organ acquisition costs for transplants are paid on a reasonable cost basis, separately from the MS-DRG (Medicare Severity Diagnosis Related Group) payment. Hospitals are paid the estimated amount for these costs through interim biweekly payments throughout the year, referred to as “pass-through amounts” (pass-through amounts include other costs as well). For MA rate calculations to date, these FFS pass-through amounts are estimated and specifically added to the inpatient claim records to account for the eventual payment in the FFS program on a reasonable cost basis. The kidney acquisition costs included in the pass-through amounts are added to all discharges from kidney transplant centers by the county of the beneficiary’s residence. Since the number of these discharges greatly exceeds the number of transplants, there is sufficient data to calculate credible kidney carve out factors and there is no need to adjust for credibility. Kidney acquisition costs are not allocated by the number of transplants. Since the pass-through KAC amounts are calculated and included at the county level, the carve-out factors must be developed at the county level to be consistent.

Comment: A commenter expressed concern about potential barriers to access to transplantation in MA, citing language in the proposed rule that stated that the transplant incidence rate for ESRD beneficiaries has historically been higher in FFS than in MA.

Response: Our data indicated that MA ESRD enrollees have been in dialysis status for a shorter duration and are typically older than FFS ESRD enrollees. We have observed that in the Medicare program, the incidence of kidney transplants is typically inversely correlated with age; the younger the ESRD enrollee, the more likely that a kidney transplant will occur. Historically, MA enrollees are less likely than FFS enrollees to receive a kidney transplant since the average age of MA ESRD enrollees is higher than the average age of FFS ESRD enrollees. It is our interpretation of this data that on average, older ESRD enrollees are not as likely to be eligible

for a kidney transplant due to other underlying health conditions that typically occur as these enrollees age. The 2020 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation outlines a comprehensive, evidence-based set of guidelines and recommendations designed to assist health care professionals assess suitability for candidacy for kidney transplantation. While clinicians are advised against excluding patients because of age alone, the guidelines recommend that they consider age in the context of other comorbidities, including frailty, which may affect outcomes. As MA enrollees have typically become eligible for Medicare due to age and disability and are, on average, older than FFS enrollees, MA ESRD enrollees may, on average, be more likely to have comorbidities that make them less suitable for kidney transplantation. As more ESRD beneficiaries enroll in MA plans, we anticipate that the profile of these beneficiaries will change and the difference in the transplant incidence rate for ESRD beneficiaries enrolled in MA and those in FFS will decrease.

After careful consideration of all comments received, we are finalizing the exclusion of kidney acquisition costs from MA benchmarks and coverage under FFS Medicare as proposed.

3. Reinsurance Exceptions (§ 422.3)

It is difficult to determine whether there would be a cost or savings impact to this proposal. The use of reinsurance or other arrangements permitted by the proposal is a choice for MA organizations, which they can exercise if they believe it is in their business interests to purchase. While purchasing reinsurance coverage has a cost associated with it, the use of reinsurance provides financial protection that may generate offsetting savings to the MA organization, or reduce their risk. Therefore, we are unable to quantitatively estimate the impacts of this provision.

We solicited stakeholder comment on i) how this provision may be used, ii) likely costs and savings, and iii) other related impacts. We received no comments on this regulatory impact analysis for this proposal and therefore are finalizing this provision without modification.

4. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

We proposed measure updates as well as the methodology changes (concerning outliers and the weight of patient experience/complaints and access measures). These measure updates are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA-PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These type of routine changes have historically had very little or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

The cost impacts due to the Star Ratings updates are calculated by quantifying the difference in the MA organization's final Star Rating with the final rule and without the final rule. There are two ways that our final rule could cause a contract's Star Rating to change: (1) to increase measure weights for patient experience/complaints and access measures from two to four; and (2) the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers. There are assumed to be Medicare Trust Fund impacts due to the Star Ratings changes associated with these two revisions to the methodology. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund, as there are more contracts that would see their Star Ratings increase than decrease. The Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund after the first year, as more contracts would see their Star Ratings decrease rather than increase.

All impacts are considered transfers since no goods or services are increased or decreased.

The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this final rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA organization, which, in turn, leads to a higher benchmark. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).
- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the MA baseline assumptions are updated with the assumed Star Ratings changes described in this final rule. The MA baseline is completed using a complicated, internal CMS model. The main inputs into the MA baseline model include enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) dual-eligible beneficiaries; (ii) beneficiaries with employer-sponsored coverage; and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include the following:

- United States Per Capita Cost (USPCC) growth rates.
- Adjustment to MA risk scores for differences in diagnosis coding between MA and fee-for-service beneficiaries.

- Quality bonus (county-specific).
- Phase-out of Indirect Medical Education (county-specific).

Projections are performed separately for payments from the Part A and Part B trust funds. Aggregate projected payments are calculated as the projected per capita cost times the projected enrollment. The Medicare Trust Fund impacts are calculated by taking the difference of the MA baseline with the Star Ratings changes and the original MA baseline.

The results are presented in Table 12. The last column of Table 12 presents net savings to the Medicare Trust Fund once both provisions are in place; in 2024 the costs are \$345.1 million; the net savings will grow over time reaching \$999.4 million by 2030. The first year only includes the implementation of the weight change, while future years include both the weight change and Tukey outlier deletion resulting in a change from the first year as a cost to the Medicare Trust Fund to a net savings in future years. The aggregate savings over 2024 to 2030 are \$4.1 billion. Ordinary inflation is carved out of these estimates. The source for ordinary inflation is Table II.D.1. of the 2019 Medicare Trustees report. It should be noted that there are inflationary factors that are used in the projected Star Ratings and are used in these estimates. The Star Ratings are assumed to inflate at a higher rate for the lower rated contracts than for the higher rated contracts. MA organizations with low Star Ratings have a better chance of improving their quality ratings than MA organizations that have already achieved a high Star Rating. For instance, a contract with a Star Rating of 4.5 has less room to increase its Star Rating than a contract with a Star Rating of 3.0.

There is a large projected reduction in the costs associated with the increase in the weight of measures classified as patient experience/complaints and access measures in 2029. This is due to several contracts that are projected to achieve a 4.0 Star Rating in 2029 and are eligible

for the QBP at that time, even after this final rule is applied. This narrows the difference in costs between the final rule and the original baseline.

The impact on costs is not seen until 2024 for the increase in weights and 2025 for the Tukey outlier deletion since these policies are being implemented for the 2021 and 2022 measurement years (meaning performance periods), respectively. A change for the 2021 measurement year impacts the 2023 Star Ratings which determines the MA QBPs for the 2024 contract year. Similarly, a change for the 2022 measurement year impacts the 2024 Star Ratings which determines the MA QBPs for the 2025 contract year.

TABLE 12: CALCULATIONS OF NET SAVINGS PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Ordinary Inflation	Increased Cost (Weight) in Patient Access and Experience/Complaints (\$ Millions)	Increased Cost (Weight) in Patient Access and Experience/Complaints (\$ Millions) With Ordinary Inflation Carved Out	Savings from Tukey Outlier Deletion (\$ Millions)	Savings from Tukey Outlier Deletion (\$ Millions) With Ordinary Inflation Carved Out	Net Savings with Ordinary Inflation Carved Out (\$ Millions)
2024	3.20%	391.4	345.1	0	0.0	-345.1
2025	3.20%	305.4	260.9	935	798.8	537.9
2026	3.20%	296.1	245.1	1,029.00	851.8	606.7
2027	3.20%	343.4	275.4	1,110.50	890.8	615.3
2028	3.20%	301.1	234.0	1,296.50	1007.7	773.7
2029	2.60%	93.9	71.1	1,356.90	1027.9	956.8
2030	2.60%	95.7	70.7	1,449.20	1070.0	999.4
Totals with inflation carved out			1502.3		5647.0	4144.6

Note: In all but the last column both costs and savings are expressed as positive numbers. Positive numbers in the last column indicate savings while negative numbers indicate net cost.

We received the following comments on our estimates of cost impacts, and our responses follow.

Comment: A couple of commenters wanted more information on the modeling related to the financial impacts.

Response: The modeling is based on taking the difference of the MA baseline with the Star Ratings changes (Tukey outlier deletion and the weight increase for patient experience/complaints and access measures) and the original MA baseline which is described in the Medicare Trustees Report available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>. CMS assumptions related to enrollment and revenue growth are available in the Medicare Trustees Report. Some commenters referenced analyses that Wakely⁵⁶ conducted that suggested a higher impact for deletion of outliers. As we are implementing these changes on top of guardrails, which will already limit significant movements of cut points from year-to-year, we do not believe that the estimates should be higher than what was included in the notice of proposed rulemaking.

As many commenters noted, the COVID-19 public health emergency does create more uncertainty in terms of how performance and quality metrics will change following the pandemic. At this time there is too much uncertainty to revise these estimates to reflect the impact of the pandemic on quality measure scores. CMS will continue to monitor the impact for additional changes.

Comment: A few commenters mentioned the analysis by Wakely referenced in the prior comment which suggests that CMS may have overestimated the weight impact on Star Ratings

⁵⁶ Wakely Consulting Group. Star Rating Variability of Patient Experience and Access Measures: Analyzing the Impact of Variable Star Rating Cut Points and Measure Level Results. March 2020.

for plans. The report also found there is significant year-over-year volatility in average Star Ratings for patient experience/complaints and access measures, despite consistent trends in plan performance over time and that increasing the weight of these measures could impact the stability of the Star Ratings program.

Response: The Wakely report claims that the volatility in cut points over time is primarily driven by the clustering methodology. CMS disagrees with this conclusion. The majority of measures included in the patient experience/complaints and access categories do not use the clustering methodology. CAHPS measure Star Ratings are calculated using relative distribution and significance testing, per §§ 422.166(a)(3) and 423.186(a)(3). CMS has seen over time that changes in measure cut points are primarily driven by differences in the distribution of scores over time and changes in industry performance. It is also not clear whether Wakely took into consideration other changes to the Star Ratings methodology over time, including the retirement of the Part D appeals and BMI measures.

In the proposed rule, CMS proposed outlier deletion using the Tukey outer fence outlier removal. The main objective of removing outliers is to stabilize cut points and prevent large year-to-year fluctuations in cut points. Even for skewed distributions, Tukey outlier removal works to stabilize cut points to avoid substantial year-to-year fluctuations in cut points that can be caused by extreme outliers.

Comment: A couple of commenters questioned the budget estimates for the new policies. They mentioned the Wakely report noting that the report estimated that increasing the weights of patient experience/complaints and access measures in the 2023 Star Ratings would only increase MA plan payments by \$83 million – nearly 5 times less than what CMS estimated. A commenter stated that when combined with the proposal to exclude outliers, more MA enrollees

would be in plans negatively impacted than those who would see positive results. The commenter requested CMS to first provide more details on its methodology to allow plans to run similar simulations to better understand the impact of the proposed change to the weighting for these measures and plan ratings

Response: It is unclear to CMS how Wakely did their simulations. For example, it appears that Wakely did not understand that the CAHPS measures are not calculated using the clustering methodology, and consequently, Tukey outlier deletion would not be applied to that group of measures. CMS simulations were conducted assuming the implementation of guardrails which limits the fluctuation in cut points and assuming the retirement of the Part D appeals and BMI measures. Wakely stated they applied mean resampling and guardrails to the Star Rating cut points prior to applying Tukey outlier deletion; therefore, the estimated impact of Tukey outlier deletion does not include the impact of mean resampling and guardrails. We specifically proposed that prior to applying mean resampling with hierarchical clustering, Tukey outer fence outliers are removed and this is how CMS conducted the simulations. This may be causing some of the discrepancies. As described above, CMS estimated the change in the ratings of MA contracts and then modeled the cost impact using that information and enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) dual-eligible beneficiaries; (ii) beneficiaries with employer-sponsored coverage; and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include the USPCC growth rates, adjustment to MA risk scores, quality bonuses (county-specific), and phase-out of indirect medical education (county-specific).

After careful consideration of all comments received, and for the reasons set forth in our responses to the related comments summarized earlier, we are finalizing our impact analysis for the Star Ratings updates to include delayed implementation of Tukey outlier deletion by one year.

5. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

Regulatory Changes to Incurred Claims (§ 422.2420)

As discussed in section IV.D.2 of this final rule, we are finalizing our proposal to amend the regulation at § 422.2420(b)(2)(i) so that the incurred claims portion of the MLR numerator for an MA contract would include all amounts that an MA organization pays (including under capitation contracts) for covered services for all enrollees under the contract. Prior to this regulatory change, § 422.2420(b)(2)(i) specified that incurred claims include direct claims that an MA organization pays to providers as defined in § 422.2 (including under capitation contracts with physicians) for covered services provided to all enrollees under the contract.

We proposed this amendment so that incurred claims in the MLR numerator will include expenditures for certain supplemental benefits that MA organizations are newly authorized to offer to MA enrollees as a result of recent policy and legislative changes. As explained in greater detail in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, recent subregulatory guidance and statutory changes have expanded the types of supplemental benefits that MA organizations may offer to enrollees. Beginning in 2020, pursuant to section 1852(a)(3)(D) of the Act, as amended by the BBA of 2018, MA organizations may provide SSBCI. SSBCI can include benefits that are not primarily health related, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function. In addition, effective January 1, 2019, CMS' interpretation of "primarily

health related benefits,” which is used as a criterion for supplemental benefits, has been changed to include services or items used to diagnose, compensate for physical impairments, ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. To be considered “primarily health related,” a supplemental benefit must focus directly on an enrollee’s health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one.

This impact analysis assumes that the amendments to § 422.2420(b)(2)(i) would not impact MA enrollee benefits. In other words, the analysis assumes the amendments would change the types of expenditures that could be included in the MLR numerator as incurred claims, but there would be no impact on the level or number of permissible enrollee benefits that MA plans elect to offer.

The requirements pertaining to the calculation and reporting of MA contracts’ MLRs are presented in 42 CFR part 422, subpart X. MA organizations that do not meet the 85 percent minimum MLR requirement for a contract year are required to remit funds to us (§ 422.2410(b)). We collect remittances by deducting the amounts owed from MA organizations’ monthly payments (§ 422.2470(c)). In the absence of statutory language directing us to return remitted funds to the Medicare Trust Fund, we transfer remittances to the Treasury. For purposes of this impact analysis, we assume contracts that have an MLR of less than 85 percent for one contract year do not continue to fail to meet the MLR requirement for an additional two consecutive contract years, which would result in imposition of enrollment sanctions, or for an additional four consecutive contract years, which would result in contract termination. This is consistent with our experience; although the MLR requirement has only been in effect for five contract

years, to date, very few contracts have been subject to MLR-related enrollment sanctions, and only one contract has failed to meet the MLR requirement for more than three consecutive contract years. No contract has been terminated for failure to meet the MLR requirement for five consecutive contract years.

Total remittances for individual contract years can be substantial. Based on internal CMS data, the simple average of total remittances across all contracts for contract years 2014 – 2017 is \$131 million. If we adjusted these payments to a 2017 level by trending for enrollment and per capita growth but carving out ordinary inflation, the average would be \$139 million.

We anticipate that the amendments to § 422.2420(b)(2)(i), which we are finalizing in this final rule, would increase the numerator of the MLR because the incurred claims category would include certain expenditures that would not qualify for inclusion in the numerator under the current regulations. Specifically, under the amendments to § 422.2420(b)(2)(i) that we are finalizing, incurred claims would include amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether payment is made to an individual or entity that is a provider as defined at § 422.2. We expect that this will cause some MA contracts which formerly would not have satisfied the 85 percent minimum MLR requirement to now meet or exceed it. For contracts that still fail to meet the 85 percent threshold, we anticipate that the amount of remittances would decrease. In other words, we anticipate that the amendments to § 422.2420(b)(2)(i) that we are finalizing will effectively result in a transfer of funds from the Treasury to the MA organizations through the Medicare Trust Fund. Amounts that MA organizations would remit and which the Treasury would receive under the regulations prior to their amendment by this final rule will instead remain with the MA organizations, implying that MA organizations will enjoy cost savings while the Treasury has a

cost impact. The net impact on the Medicare Trust Fund is expected to be zero, since there will be no additional transfers from or to the Medicare Trust Fund; the only issue will be whether the MA organizations retain additional funds or the Treasury receives fewer funds.

To estimate the amount of payments made for services that would be included in incurred claims under the amendments to § 422.2420(b)(2)(i) that we are finalizing, we used data in the 2019 submitted bids to estimate the increase in the supplemental benefits category for the primarily health related benefits that MA organizations could include in their PBPs starting in 2019. This estimate is complicated by the fact that, in the absence of the amendments to § 422.2420(b)(2)(i), some types of supplemental benefits that MA organizations could offer starting in 2019 could potentially meet the requirements at § 422.2430 to be quality improvement activities (QIAs) for MLR purposes, meaning expenditures for those benefits could be included in the MLR numerator. Based on the 2019 submitted bid information, a consideration of the types of benefits that MA organizations could offer under our reinterpretation of the “primarily health related” definition, and the likelihood that some of these benefits would meet the requirements at § 422.2430(a) to be QIAs, we estimated a 52 percent increase in projected expenditures for the categories of “primarily health related” supplemental benefits that would not qualify for inclusion in the MLR numerator as “incurred claims” under § 422.2420(b)(2)(i), as defined prior to the amendment that we are finalizing in this final rule, or as QIA under § 422.2430(a). The first year that the expanded interpretation of “primarily health related benefits” was implemented was 2019, and so the increase seen in these categories for 2019 is attributed to this reinterpretation. To date, MA organizations have only been able to include non-primarily health related SSBCI in their plan offerings for one year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to

grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Due to the absence of credible data for SSBCI, the impact on future MLR remittances is currently unquantifiable. We will continue to track SSBCI information and adjust the forecasts as more information becomes available.

We then reevaluated the MLRs for those contracts that failed to meet the 85 percent MLR requirement for contract years 2014 – 2017 by revising the numerator calculation to incorporate the 52 percent increase in the previously listed benefits. The change in the numerator calculation resulted in several of the contracts passing the MLR requirement instead of failing. For contracts that would not have met the MLR requirement even with the revised numerator calculation, the amount of remittances decreased. The average decrease in remittance payments over the four-year period (that is, 2014 – 2017) is estimated to be \$25.8 million (in 2017 dollars).

In order to project the decrease in remittances for the years 2021 – 2030, the \$25.8 million was increased using estimated enrollment and per capita increases based on Tables IV.C1 and IV.C3 of the 2019 Medicare Trustees Report, with ordinary inflation (Table II.D1 of the 2019 Medicare Trustees Report) carved out of the estimates.

The results are presented in Table 13, which shows that for the first year of the finalized provision, 2021, there will effectively be a transfer from the Treasury through the Medicare Trust Fund of \$35.3 million to MA organizations. (For computational transparency, the table also shows the amounts that would have been transferred to MA organizations for 2017 – 2020 if the change we are finalizing in this final rule had been in place in those years.) This transfer is in the form of a reduction in the remittance amounts withheld from MA capitated payments. This amount (that is, the amount of remittances *not* withheld from MA capitated payments under the finalized provision) is projected to grow over 10 years, resulting in a \$56.4 million transfer from

the Treasury through the Medicare Trust Fund to MA organizations in 2030. The total transfer from the Treasury to MA organizations over 10 years is \$455 million. There is \$0 impact on the Medicare Trust Fund.

TABLE 13: TRANSFER OF REMITTANCES FROM THE TREASURY TO MA ORGANIZATIONS

Year	Medicare Advantage Enrollment Increase	Average Annual Per Capita Increase	Ordinary Inflation	Net costs (\$ millions)
2017				25.8
2018	7.7%	5.5%	3.2%	28.4
2019	6.7%	5.5%	3.2%	31.0
2020	5.0%	5.5%	3.2%	33.3
2021	3.6%	5.5%	3.2%	35.3
2022	3.8%	5.5%	3.2%	37.5
2023	3.5%	5.5%	3.2%	39.7
2024	3.3%	5.5%	3.2%	41.9
2025	3.1%	5.5%	3.2%	44.2
2026	3.0%	5.5%	3.2%	46.5
2027	2.7%	5.5%	3.2%	48.8
2028	2.5%	5.5%	3.2%	51.1
2029	2.3%	5.5%	2.6%	53.8
2030	2.0%	5.5%	2.6%	56.4
Total 2021-2030				455.2

We received no comments on our impact analysis and are finalizing the proposal without modification.

Deductible Factor for MA Medical Savings Account (MSA) Contracts (§422.2440)

As discussed in section IV.D.4. of this final rule, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor will serve as a multiplier on the credibility factor. We are also finalizing our proposal to adopt and codify in new paragraph (g) of § 422.2440 the same deductible factors that appear in the commercial MLR

regulations at 45 CFR 158.232(c)(2). For partially credible MA MSA contracts, the deductible factor will range from 1.0 for MA MSA contracts that have a weighted average deductible of less than \$2,500 to 1.736 for MA MSA contracts have a weighted average deductible of \$10,000 or more.

In section IV.D.4. of this final rule, we explain that we proposed to add a deductible factor to the MLR calculation for MSAs so that organizations currently offering MSA plans, or those that are considering entering the market, are not deterred from offering MSAs due to concern that they will be unable to meet the MLR requirement as a result of random variations in claims experience. Although we believe that the deductible factors would adequately address any such concerns by making it less likely that an MSA contract will fail to meet the MLR requirement due to random variations in claims experience, we are uncertain whether or how the proposed change to the MLR calculation for MA MSA contracts will impact the availability of MA MSAs or the number of beneficiaries enrolled in MA MSAs. Due to this uncertainty, we estimate that the cost impact of the change to the MLR calculation for MA MSAs will be as low as \$0 or as high as \$40 million over 10 years (2021 – 2030).

We do not anticipate that applying a deductible factor to the MLR calculation for MA MSA contracts will have an impact on remittances to the federal government. For contract years 2014 – 2018 (the most recent contract year for which MA MSAs have submitted MLR data), no MA MSA contract has failed to meet the 85 percent minimum MLR requirement. If the deductible factor had applied to the MLR calculation for MA MSAs for contract years 2014 – 2018, although the MLRs for partially credible MA MSAs would have been higher, total remittances by MA MSAs would have remained at \$0. We do not anticipate that MSA contracts that currently meet the MLR requirement will have more difficulty doing so after the deductible

factor is applied to the MLR calculation, starting in contract year 2021. We anticipate that new MA MSA contracts that MA organizations may choose to offer as a result of this regulatory change will also succeed in meeting the MLR requirement, in light of the experience of current MSAs and in consideration of the more generous credibility adjustment that potential new MSAs would be expected to receive as a result of the application of the deductible factor.

We believe that the cost impact of this regulatory change, if any, will be attributable to an increase in MA MSA enrollment as these plans become more widely available as a result of MA organizations choosing to offer MA MSAs in response to the change to the MLR calculation. To develop the upper limit of the cost estimate for this impact analysis (\$40 million over 10 years), we assumed that the change to the MLR calculation for MSAs would cause MA MSA enrollment to double over the first 3 years that the change is in effect. We estimated that, relative to previous enrollment projections that did not account for the amendments that we are finalizing in this final rule, this regulatory change MSA enrollment will be 33.33 percent higher in 2022, 66.67 percent higher in 2023, and 100 percent higher in 2024 to 2030. We assumed that half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare.

We did consider the migration patterns for EGWP ESRD beneficiaries versus Individual ESRD beneficiaries. We surmised that the costs differences between EGWP and Individual ESRD coverages are not significant enough to display the migration patterns separately. Displaying projections at that coverage level would not provide further understanding of the financial projections since the cost differences are not too different. Furthermore, EGWP plans have not submitted bids since 2017 and their payments are based on aggregated Individual bids so the cost differences would not be expected to be too different.

We then determined the difference between the amount we pay for each MA MSA plan enrollee and the amount we pay for each enrollee in a non-MSA MA plan or FFS Medicare. We generally incur greater costs for MA MSA enrollees relative to enrollees in other MA plans because 100 percent of the difference between the MA MSA’s projection of the cost of A/B services (referred to as the MSA premium) and the benchmark is deposited in the enrollee’s account. By contrast, for non-MSA MA plans that bid under the benchmark, we retain between 30 percent and 50 percent of the amount by which the benchmark exceeds the bid. FFS spending per enrollee is approximately 100 percent of the amount we pay to MA plans for each enrollee. Therefore, the cost to the Medicare program for each additional MA MSA enrollee is approximately the same regardless of whether the enrollee would otherwise have been enrolled in a non-MSA MA plan or in FFS Medicare.

The estimated annual cost to the Medicare Trust fund by contract year is presented in Table 14. This estimate takes into account the projected growth in MSA enrollment in the Part C baseline projection supporting the Mid-Session Review of the FY 2020 President’s Budget. The estimated annual cost reflects the additional cost to the Medicare program for each beneficiary who enrolls in an MA MSA plan in lieu of a non-MSA MA plan or FFS Medicare, multiplied by the projected increase in the number of enrollees in MA MSA plans.

TABLE 14: ESTIMATED COST PER YEAR TO THE MEDICARE TRUST FUND FOR CHANGES TO MLR CALCULATION FOR MA MSA CONTRACTS

Contract Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021-2030
Annual cost (millions)	\$0.0	\$1.2	\$2.4	\$4.0	\$4.4	\$4.8	\$5.2	\$5.6	\$6.0	\$6.4	\$40.0
Proposed Annual Increase in MA MSA Enrollment	0	2,604	5,453	8,531	8,876	9,213	9,531	9,833	10,118	10,354	-

We received no comments on our impact analysis and are finalizing the proposal without modification.

6. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Our final rule codifies the standards and methodology used currently, with some modifications, to evaluate network adequacy for MA plans and section 1876 cost plans; the final rule includes the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards and minimum number requirements. The final rule also formalizes the CMS exceptions process and requires the annual publishing of the Health Services Delivery (HSD) reference file, which will provide updated numbers and maximums for these standards in subsequent years, and the Provider Supply File, which lists available providers and facilities, including their corresponding office locations and specialty types. CMS will continue to use the current PRA-approved collection of information in conjunction with the HPMS Network Management Module as a means for MA organizations to submit network information when required. As this has been the process for conducting network adequacy reviews since 2016, we do not expect any additional burden on MA plans as it relates to the network adequacy review process.

Our final rule is solely related to the sufficiency of contracted networks that MA organizations must maintain and has no impact on the provision of Medicare benefits that must be provided in either in-network and out-of-network settings. As a result, we do not expect any impact on the Medicare Trust Fund.

However, we are finalizing three modifications to current network adequacy policy that may have qualitative impacts on MA organizations. In Micro, Rural, and CEAC county designation types, we are reducing the percentage of beneficiaries residing within maximum time

and distance standards from 90 percent to 85 percent. We will allow for a 10-percentage point credit towards the percentage of beneficiaries residing within maximum time and distance when MA organizations contract with one or more telehealth providers in the specialties of Dermatology, Psychiatry, Neurology, Otolaryngology, Cardiology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/ OB/GYN, Endocrinology, and Infectious Diseases. Similarly, MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, if the laws limit the number of providers or facilities in a county or state.

With respect to the reduction in percentage of beneficiaries residing within maximum time and distance standards in rural counties, we expect that MA organizations will have a greater likelihood of complying with our reduced percentage in the initial network submission and will not need to request an exception for CMS's consideration. It is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, as they are submitted for multiple reasons. However, generally, we expect that this change will decrease the administrative burden on MA organizations when going through the network review process. Conceivably, the administrative costs included in an MA organization's bid could decrease. However, the decrease in administrative burden could be offset by the increase in administrative burden of contracting with telehealth providers. Additionally, more MA organizations may consider providing contracted services in areas that have traditionally been difficult to establish a sufficient network. The ability to meet compliance standards in new markets is a reasonable factor that may drive MA organization behavior, but we cannot quantify the likelihood of this, as many other factors are considered when entering new markets. In

theory, the reduction in the rural percentage could conceivably increase MA enrollment, however our enrollment projections currently do not consider health plans' network adequacy information, and any changes to enrollment projections would be very minor.

By crediting MA organizations 10-percentage points towards the percentage of beneficiaries residing within time and distance standards for contracting with telehealth providers for certain specialties, we anticipate that this will be one of many factors that will help encourage MA organizations to contract with providers that offer telehealth services. However, we do not expect this policy change to significantly alter MA organization contracting patterns related to telehealth providers.

For the 10-percentage point credit for affected providers and facilities in states with CON laws, we expect that MA organizations will have a greater likelihood of complying with network adequacy standards in the initial network submission and will not need to request an exception for CMS's consideration. As we discussed earlier, it is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, but it is possible the administrative costs included in an MA organization's bid could decrease. However, we believe time associated with completing exception requests is nominal will not have a significant impact on the overall administrative costs submitted in a plan's bid.

In summary, we believe this proposal will have a non-quantifiable, negligible economic impact. We received no comments on the regulatory impact of this proposal, and therefore, we are finalizing this provision without modification.

E. Alternatives Considered

We intend to address the proposals that had Alternatives Considered sections from the February 2020 proposed rule in subsequent rulemaking. CMS did not develop Alternatives

Considered sections for most of the provisions in this final rule as they generally are direct implementations of federal laws or codifications of existing policy for the Part C and D programs. In this section, CMS includes discussions of Alternatives Considered for the provisions to which they are applicable.

1. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

We have considered alternatives to estimated costs to the Medicare Trust Funds for removing the prohibition for ESRD beneficiaries to enroll in MA plans. Table 7 above displays the baseline scenario that ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years, with half of the beneficiaries (41,500) enrolling during 2021. Table 7 shows the net cost to range from \$23 million in CY 2021 to \$440 million in CY 2030 which sums to \$2.66 billion cost for those 10 years.

The upper scenario uses the assumption that the entire ESRD enrollment increase in MA plans of 83,000 will occur in 2021. All other assumptions are expected to remain the same as those in the baseline. Under this upper scenario, net costs are expected to range from \$45 million in CY 2021 to \$440 million in CY2030 which sums to \$2.73 billion cost for the 10 year projection period.

The lower scenario uses a slower ESRD enrollment increase assumption. Under this scenario, the ESRD enrollment will linearly increase from 8,300 in 2021 to 83,000 in 2030. All other assumptions are expected to remain the same as those in the baseline. Under this lower scenario, net costs are expected to range from \$5 million in CY 2021 to \$440 million in CY2030 which sums to \$1.87 billion cost for the 10 year projection period.

2. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We have considered alternative methodologies for deleting outliers prior to clustering for determining cut points for non-CAHPS measures for the Star Ratings program.

For example, we have considered trimming, which removes scores below and above a certain percentile. As stated in the NPRM, this methodology would remove scores regardless of whether they are true outliers; thus, this methodology would not meet the policy goal of removing outliers as well as the approach we proposed and might not have a negligible impact on the cost estimates.

For the Tukey outlier deletion provision as described in section VIII.D.5. of this final rule, we considered which year it should begin. In the NPRM we proposed for it to begin for the 2021 measurement year, which impacts the 2023 Star Ratings and 2024 Quality Bonus Payment ratings. To provide more time for the healthcare delivery system to adapt to changes from the COVID-19 pandemic, we are finalizing a delay until the 2022 measurement year, which impacts the 2024 Star Ratings and the 2025 Quality Bonus Payment ratings. The cost impact of this change is \$713 million (that is, this amount will not be saved from the Medicare Trust Fund in 2024).

We have also considered alternatives to the doubling of the weight from 2 to 4 for patient experience/complaints measures and access measures for the Star Ratings program as described in section VIII.D.5. of this final rule. For example, we considered a weight increase to 3 or 5 for these measures. With a weight increase to 3, there are very small changes in the number of contracts that would increase their highest Star Rating, resulting in negligible impacts on Quality Bonus Payments and costs to the Medicare Trust Fund relative to a weight of 4.

Similarly, if we were to increase the weight even further to 5, we anticipate even greater impacts on the Quality Bonus Payments and, consequently, costs to the Medicare Trust Fund.

Finally, we considered delaying any weight increase given the uncertainty about how COVID-19 will impact the healthcare system; however, we decided to proceed to further emphasize the importance of patient experience/complaints measures and access measures.

3. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We considered finalizing the proposal to add a deductible factor to the MLR calculation for MA MSA contracts (section VIII.D.6. of this final rule) with an applicability date of January 1, 2022, rather than January 1, 2021, since this rule is not being finalized until after the deadline for MA organizations to apply to offer MSA plans in 2021. However, as discussed in greater detail in section IV.D.4. of this final rule, we believe that the credibility factors used to adjust the MLRs of low enrollment contracts do not adequately account for the impact of claims variability on the MLRs of high deductible MSA contracts. We therefore believe it is appropriate that we finalize the provision to add a deductible factor to the MLR calculation for MA MSA contracts with an applicability date of January 1, 2021, as this will allow the deductible factor to be applied when calculating the contract year 2021 MLRs for current MA MSA contracts. However, as no current MA MSA contract has failed to meet the minimum MLR requirement for a previous contract year, we do not anticipate that applying a deductible factor to those contracts' contract year 2021 MLRs will have an impact on remittances.

F. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A-4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 15, we have prepared

an accounting statement showing the savings, costs, and transfers associated with the provisions of this final rule for calendar years 2021 through 2030. Table 15 is based on Tables 16A, 16B, and 16C which lists savings, costs, and transfers by provision. Table 15 is expressed in millions of dollars with both costs and savings listed as positive numbers; aggregate impact is expressed as a negative number (cost versus savings). The sign of the transfers follow the convention of Table 16 with positive numbers reflecting costs (as transfers) to government entities (the Medicare Trust Fund and the Treasury) and negative numbers reflecting savings to government entities. As can be seen, the net annualized impact of this rule is a cost of about \$1.9 million per year. The raw aggregate cost over 10 years is \$18.5 million. Due to transfers, there is net annualized reduced spending by government agencies (the Medicare Trust Fund and Treasury) of \$290 - \$335 million. A breakdown of these savings from various perspectives may be found in Table 16.

TABLE 15: ACCOUNTING TABLE (MILLIONS \$)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Savings	(1.9)	(1.9)	Contract Years 2021-2030	Federal government, MA organizations and Part D Sponsors
Annualized Monetized Savings	-	-	Contract Years 2021-2030	
Annualized Monetized Cost	1.9	1.9	Contract Years 2021-2030	Federal government, MA organizations and Part D Sponsors
Transfers	(293.7)	(334.5)	Contract Years 2021-2030	Transfers between the Dept of Treasury and CMS (Medicare Trust Fund, Plans, and Sponsors)

* The ESRD enrollment and Kidney acquisition cost provisions which affected the pre-statutory baseline but did not further impact the codifications of this rule would have added \$128.3 and \$113.1 million respectively in annualized transfer savings, resulting in total annualized transfer savings of \$421.99 and \$447.65 savings at 7 percent and 3 percent respectively. Note: Negative numbers indicate a net reduction in dollar spending by the government.

The following Table 16 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 16 is broken into Table 16A (2021 through 2024), Table 16B (2025 through 2028), and Table 16C (2029-2030), as well as raw totals. In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs and does not include transfers. All numbers are in millions. Tables 16A, B, and C form the basis for Table 15.

TABLE 16A: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2021 THROUGH 2024

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 Cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	-			-			-			-		
Total Costs		2.1			1.8			1.8			1.8	
Aggregate Total	(2.1)			(1.8)			(1.8)			(1.8)		
Total Transfers			35.3			38.1			40.9			389.0
Health Plan Quality Rating system												345.1
Medical Loss Ratio Regulation			35.30			37.50			39.70			41.9
MSA MLR						0.6			1.2			2.0
SSBCI		2.1			1.8			1.8			1.8	

TABLE 16B: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 THROUGH 2028

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Total Savings	-			-			-			-		
Total Costs		1.8			1.8			1.8			1.8	
Aggregate Total	(1.8)			(1.8)			(1.8)			(1.8)		
Total Transfers			(491.5)			(557.8)			(563.9)			(719.8)
Health Plan Quality Rating system			(537.9)			(606.7)			(615.3)	-		(773.7)
Medical Loss Ratio Regulation			44.2			46.5			48.8			51.1
MSA MLR			2.2			2.4			2.6			2.8
SSBCI		1.8			1.8			1.8			1.8	

TABLE 16C: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2029 THROUGH 2030 AND RAW TOTALS

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)	Raw 10 year totals (Transfers)
Total Savings	-			-			-		
Total Costs		1.8			1.8			18.5	
Aggregate Total	(1.8)			(1.8)			(18.5)		
Total Transfers			(900.0)			(939.8)			(3,669.4)
Health Plan Quality Rating system			(956.8)			(999.4)			(4,144.6)
Medical Loss Ratio Regulation			53.8			56.4			455.2
MSA MLR			3.0			3.2			20.0
SSBCI		1.8			1.8			18.5	

The following information supplements Table 16 and also identifies how impacts calculated in section VII of this final rule affect the calculations of this section and the tables.

- Table 16 includes a row for the paperwork burden of the SSBCI provision, whose impact is about \$1 million a year.
- For the transfer rows, positive numbers indicate transfers that result in increased dollar spending by the government, while negative numbers indicate transfers that result in reduced dollar spending by the government. Costs are expressed as positive numbers; however, net savings are expressed as negative numbers to reflect that the net impact is a cost, not a savings.
- For two provisions, Parts C and D SEPs, and ESRD enrollment, calculations of impact, either paperwork impact or Medicare Trust Fund impact, have been provided in the narrative along with tables providing 10-year summaries. However, since these impacts are already reflected in current spending, in other words, since the provisions do not change current spending, these impacts have not been included in Table 16. Similarly, as explained in section VII, since the SSBCI paperwork burden is already being spent (similar to SEP), the burden is not included in the summary table.
- Besides the enrollment burden for the SEP provision, there is an additional cost of \$0.5 million arising from burden to beneficiaries for filling out enrollment forms in several provisions. These costs have been duly noted in section VII of this final rule but were not included in Table 16 since Table 16 deals mainly with impacts on the Medicare Trust Fund and industry.

- For two provisions, D-SNP look alike and MSA MLR, the impact calculated in section VII of this final rule is \$0.0 million and hence these amounts are not included in Table 16. They are however included in Table 6 of section VII of this final rule.

We received comments on impacts in certain individual provisions. These comments as well as our responses have been addressed in the appropriate provision sections above. However, none of these comments led to changes in impacts. Additionally, we did not receive any comments on the summary or monetized table and are therefore finalizing these numbers as is with appropriate adjustments for provisions not included in this first final rule.

G. Conclusion

As indicated in Table 16, while the SSBCI provision has a paperwork burden of about \$1 million per year, the other provisions of this final rule are all classified as transfers because consumption of goods or usage of services is neither increased nor decreased. However, we note that the provisions of this part 1 of this final rule will reduce dollar spending of the government by about \$300 million a year. The primary driver of this is the Tukey outlier provision.

As indicated in Table 16, the government agencies have a net reduction in spending of \$3.65 billion over 10 years. The driver of reduction is the use of the Tukey outlier deletion for Star Ratings after the first year of implementation. Other provisions also affect government spending: 1) The MLR provisions will reduce civil penalties to the Treasury by about 0.46 billion; 2) the MLA MSR provisions will cost the government an extra \$40 million due to increased spending on benefits arising from expected increased MSA enrollment; 3) the increased weight in patient experience/complaints and access measures and Tukey outlier deletion in the health plan quality rating system (Star Ratings) will reduce Medicare Trust Fund spending by about \$1.5 billion.

H. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This rule has an aggregate cost of \$1 million a year arising from paperwork burden associated with the SSBCI provision, and consequently, this rule is classified as a regulatory action for the purposes of Executive Order 13771. At a 7 percent rate, this rule is estimated to cost \$1.2 million a year in 2016 dollars over an infinite horizon.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e-5, and 300e-9, and 31 U.S.C. 9701.

2. Section 417.416 is amended by adding paragraph (e)(3) to read as follows:

§ 417.416 Qualifying condition: Furnishing of services.

* * * * *

(e) * * *

(3) The HMO or CMP must meet network adequacy standards specified in § 422.116 of this chapter.

PART 422—MEDICARE ADVANTAGE PROGRAM

3. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

4. Section 422.3 is added to read as follows:

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee in either of the following ways--

(1) The MA organization must retain risk for at least the first \$10,000 in costs per individual enrollee for providing basic benefits during a contract year; or

(2) If the MA organization uses insurance or makes other arrangements for sharing such costs proportionately on a per member per year first dollar basis, the MA organization must retain risk based on the following:

(i) The actuarially equivalent value of the retained risk is greater than or equal to the value of risk retained in paragraph (a)(1) of this section.

(ii) The MA organization makes a determination of actuarial equivalence based on reasonable actuarial methods. For example, a reasonable method for determining actuarial equivalence would be to equate the percentage of net claim costs that the MA organization would retain under paragraphs (a)(1) and (a)(2)(i) of this section.

(b) In evaluating compliance with section 1855(b) of the Act and with paragraph (a) of this section, CMS will consider a parent organization and any of its subsidiaries to be part of the MA organization.

(c) The type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act (that is, the financial risk on a prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by paragraph (a) of this section.

§ 422.50 [Amended]

5. Section 422.50 is amended in paragraph (a)(2) introductory text by removing the phrase "Has not been" and adding in its place the phrase "For coverage before January 1, 2021, has not been".

§ 422.52 [Amended]

6. Section 422.52 is amended in paragraph (c) by removing the phrase "CMS may waive § 422.50(a)(2)" and adding in its place the phrase "For plan years beginning before January 1, 2021, CMS may waive § 422.50(a)(2)".

7. Section 422.62 is amended by--

- a. Revising paragraphs (b) introductory text and (b)(3) introductory text;
- b. Redesignating paragraph (b)(4) as paragraph (b)(26); and
- c. Adding a new paragraph (b)(4) and paragraphs (b)(5) through (25).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) *Special election periods (SEPs)*. An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(3) The individual demonstrates to CMS that—

* * * * *

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than

the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a “trial period” and eligible for “guaranteed issue” of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided--

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the

individual receives the notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA-PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after

enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA-PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA-PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA-PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA-PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by an emergency or major disaster declared by a Federal, state or local government entity are eligible for a SEP to make a MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual--

(i)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (b)(18), in an area for which a federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(ii) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (b)(18); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA-PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA-PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA-PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA-PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA

plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

* * * * *

8. Section 422.68 is amended by revising paragraph (d) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

10. Section 422.102 is amended by adding paragraph (f) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) *Special supplemental benefits for the chronically ill (SSBCI)--(1) Requirements--(i) Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

- (1) Is life threatening or significantly limits the overall health or function of the enrollee;
- (2) Has a high risk of hospitalization of other adverse health outcomes; and
- (3) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets the standard in this paragraph (f)(1)(ii) may also include a benefit that is not primarily health related.

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Must have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii) Must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria.

(iv) Document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request.

§ 422.110 [Amended]

11. Section 422.110 is amended in paragraph (b) by removing the phrase "An MA organization" and adding in its place the phrase "For coverage before January 1, 2021, an MA organization".

12. Section 422.116 is added to read as follows:

§ 422.116 Network adequacy.

(a) *General rules--(1) Access.* (i) A network-based MA plan, as described in § 422.114(a)(3)(ii) but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(2) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(ii) CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area.

(2) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary (in the MA Medicare Sample Census) in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(3) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

- (A) Specialized, long-term care, and pediatric/children's hospitals.
- (B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) [Reserved]

(4) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph

(b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.

(ii) Allergy and Immunology.

- (iii) Cardiology.
- (iv) Chiropractor.
- (v) Dermatology.
- (vi) Endocrinology.
- (vii) ENT/Otolaryngology.
- (viii) Gastroenterology.
- (ix) General Surgery.
- (x) Gynecology, OB/GYN.
- (xi) Infectious Diseases.
- (xii) Nephrology.
- (xiii) Neurology.
- (xiv) Neurosurgery.
- (xv) Oncology - Medical, Surgical.
- (xvi) Oncology - Radiation/Radiation Oncology.
- (xvii) Ophthalmology.
- (xviii) Orthopedic Surgery.
- (xix) Physiatry, Rehabilitative Medicine.
- (xx) Plastic Surgery.
- (xxi) Podiatry.
- (xxii) Psychiatry.
- (xxiii) Pulmonology.
- (xxiv) Rheumatology.
- (xxv) Urology.

(xxvi) Vascular Surgery.

(xxvii) Cardiothoracic Surgery.

(2) *Facility-specialty types*. The facility specialty types are as follows:

(i) Acute Inpatient Hospitals.

(ii) Cardiac Surgery Program.

(iii) Cardiac Catheterization Services.

(iv) Critical Care Services – Intensive Care Units (ICU).

(v) Surgical Services (Outpatient or ASC).

(vi) Skilled Nursing Facilities.

(vii) Diagnostic Radiology.

(viii) Mammography.

(ix) Physical Therapy.

(x) Occupational Therapy.

(xi) Speech Therapy.

(xii) Inpatient Psychiatric Facility Services.

(xiii) Outpatient Infusion/Chemotherapy.

(3) *Removal of a provider or facility-specialty type*. CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations*. Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro*. A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro*. A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro*. A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural*. A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal to 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC)*. For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards--(1) General rule*. CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation.* The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

Table 1 to Paragraph (d)(2)

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology - Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology - Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services – Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* When necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

- (i) Dermatology.
- (ii) Psychiatry.
- (iii) Cardiology.
- (iv) Neurology.
- (v) Otolaryngology.
- (vi) Ophthalmology.
- (vii) Allergy and Immunology.
- (viii) Nephrology.
- (ix) Primary Care.
- (x) Gynecology/ OB/GYN.
- (xi) Endocrinology.
- (xii) Infectious Diseases.

(6) *State Certificate of Need (CON) laws.* In a State with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the State or a county in the State, CMS will award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must--

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

Table 2 to Paragraph (e)(3)(i)(C)

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology - Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology - Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (1) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(2) CMS uses its MA State/County Penetration data to calculate the total number of beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (1) The 95th percentile base population ratio is:

(i) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(ii) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(2) CMS calculates the 95th percentile base population ratio as follows:

(i) Uses its most recent List of PFFS Network Counties to exclude any private-fee-for-service (PFFS) plans in non-networked counties from the calculation at the county-type level.

(ii) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(iii) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in regional preferred provider organization (RPPO), local preferred provider organization (LPPO), HMO, HMO/provider sponsored organization (POS), healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(iv) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(v) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether--

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

13. Section 422.162 is amended in paragraph (a) by adding a definition for “Tukey outer fence outliers” in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) ***

Tukey outer fence outliers are measure scores that are below a certain point (first quartile - 3.0 x (third quartile - first quartile)) or above a certain point (third quartile + 3.0 x (third quartile - first quartile)).

* * * * *

14. Section 422.166 is amended--

a. By revising paragraph (a)(2)(i); and

b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase "weight of 2" and adding in its place "weight of 4".

The revision reads as follows:

§ 422.166 Calculation of Star Ratings.

(a) ***

(2) ***

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

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§ 422.258 [Amended]

15. Section 422.258 is amended in paragraphs (d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) by removing the reference "§422.306(c)" and adding in its place the reference " §422.306(c) and (d)".

165. Section 422.306 is amended--

a. In the introductory text by:

i. Removing “§§422.308(b) and 422.308(g)” and adding in its place “§422.308(b) and (g)”; and

ii. Removing the phrase "year under paragraph (c) of this section" and adding in its place the phrase "year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section"; and

b. By adding paragraph (d).

The addition reads as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary’s estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

§ 422.312 [Amended]

17. Section 422.312 is amended--

a. In paragraph (b)(1) by removing the phrase "45 days" and adding in its place the phrase "60 days"; and

b. In paragraph (b)(2) by removing the phrase "15 days" and adding in its place the phrase "30 days".

18. Section 422.322 is amended by adding paragraph (d) to read as follows:

§ 422.322 Source of payment and effect of MA plan election on payment.

* * * * *

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

19. Section 422.514 is amended by--

a. Revising the section heading and the heading for paragraph (a).

b. Adding paragraphs (d), (e), and (f).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* * * *

* * * * *

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not:

(1) Enter into a contract under this subpart, for plan year 2022 and subsequent years, for a new MA plan that –

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under title XIX.

(2) Renew a contract under this subpart, for plan year 2023 and subsequent years, for an MA plan that –

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment–

(i) Would not meet the criteria in paragraph (d)(2)(ii) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a Specialized MA plan for Special Needs Individuals as defined in § 422.2);

(ii) Is an MA-PD plan described at § 422.2;

(iii) Has a combined Part C and Part D premium of \$0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter; and

(iv) Is of the same plan type (for example, HMO or PPO) as the plan specified in paragraph (d)(2) of this section.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if--

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA-PD plan into which individuals are transitioned describes changes to MA-PD benefits and provides information about the MA-PD plan in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send a written notice to enrollees who are not transitioned, consistent with § 422.506(a)(2).

(f) *Special considerations.* Actions taken pursuant to paragraph (d) of this section warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion in accordance with §§ 422.502(b)(3)

and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

20. Section 422.2420 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 422.2420 Calculation of the medical loss ratio.

* * * * *

(b) * * *

(2) * * *

(i) Amounts that the MA organization pays (including under capitation contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

* * * * *

21. Section 422.2440 is revised to read as follows:

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under §422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

Table 1 to § 422.2440--Base Credibility Factors for MA Contracts

Member Months	Base Credibility Factor (additional percentage points)
< 2,400	N/A (Non-credible)
2,400	8.4%
6,000	5.3%
12,000	3.7%
24,000	2.6%
60,000	1.7%
120,000	1.2%
180,000	1.0%
> 180,000	0.0% (Fully credible)

Table 2 to § 422.2440--Deductible Factors for MA MSA Contracts

Weighted Average Deductible	Deductible Factor
< \$2,500	1.000
\$2,500	1.164
\$5,000	1.402
≥ \$10,000	1.736

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

22. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

23. Section 423.38 is amended by revising paragraph (c)(8) and adding paragraphs (c)(11) through (34) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

(i) Failure to provide the individual on a timely basis benefits available under the plan.

(ii) Failure to provide benefits in accordance with applicable quality standards.

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

* * * * *

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends 2 months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is non-renewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B (January through March) for an effective date of July 1st are eligible to request enrollment in a Part D plan that begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that contract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by an emergency or major disaster declared by a federal, state or local government entity are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual--

(i)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for which a Federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area;

(ii) Was eligible for another election period at the time of SEP eligibility period described in this paragraph (c)(23); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(24) The individual is using the SEP at § 422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at § 422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at § 422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at § 422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at § 422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing Part D plan.

(33) The individual was involuntarily disenrolled from an MA-PD plan due to loss of Part B but continues to be entitled to Part A. This SEP begins when the individual is advised of the loss of Part B and continues for 2 additional months.

(34) The individual meets other exceptional circumstances as CMS may provide.

* * * * *

24. Section 423.40 is amended by revising paragraph (c) to read as follows:

§ 423.40 Effective dates.

* * * * *

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in

coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

25. Section 423.182 is amended in paragraph (a) by adding a definition for “Tukey outer fence outliers” in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile - 3.0 x (third quartile - first quartile)) or above a certain point (third quartile + 3.0 x (third quartile - first quartile)).

* * * * *

26. Section 423.186 is amended—

a. By revising paragraph (a)(2)(i); and

b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase "weight of 2" and adding in its place "weight of 4".

The revision reads as follows:

§ 423.186 Calculation of Star Ratings.

(a) ***

(2) ***

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year’s data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS

measures do not increase or decrease more than the value of the cap from one year to the next. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

27. Section 423.329 is amended by revising paragraph (b)(4) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(b) * * *

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the Advance Notice and Rate Announcement publications specified under § 422.312 of this chapter.

* * * * *

28. Section 423.2440 is revised to read as follows:

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

Table 1 to § 423.2440--Credibility Adjustments for Part D Contracts

Member Months	Credibility Adjustment (additional percentage points)
< 4,800	N/A (Non-credible)
4,800	8.4%
12,000	5.3%
24,000	3.7%
48,000	2.6%
120,000	1.7%
240,000	1.2%
360,000	1.0%
> 360,000	0.0% (Fully credible)

Dated: May 7, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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